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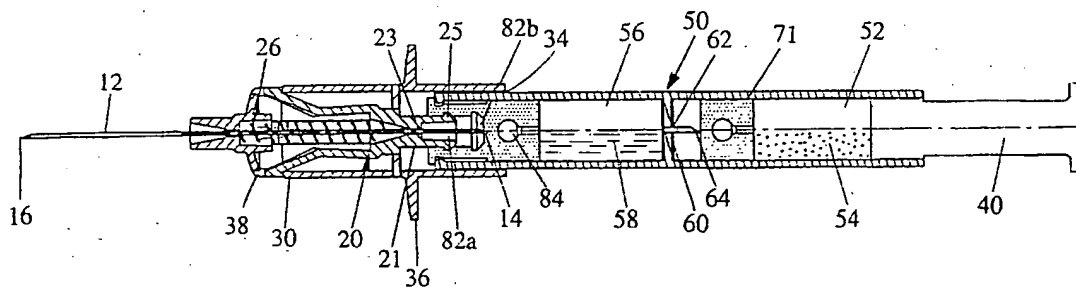
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(54) Title: PRE-FILLED SAFETY DILUENT INJECTOR



(57) Abstract: A safety needle-bearing device (10, 110, 210, 310) for mixing and injecting medication from a two-chambered cartridge (50, 150, 250, 350) is provided. The device includes a needle (12, 112, 212, 312) that extends through the forward end of a barrel (30, 130, 230, 330). The two-chambered cartridge (50, 150, 250, 350) is attached to the barrel (30, 130, 230, 330) and contains components of a medication stored separately in the chambers. A plunger (40, 140, 240) in the rearward end of the cartridge can be advanced into the cartridge to combine the separate components and prepare the medication. As the cartridge (50, 150, 250, 350) is advanced forwardly into the barrel (30, 130, 230, 330), the medication is injected through the needle (12, 112, 212, 312) and into a patient. At the completion of the injection stroke, the cartridge (50, 150, 250, 350) engages a needle retainer to actuate needle retraction. The needle is subsequently retracted to shield the contaminated needle.

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,637,087 A (O'NEIL et al.) 10 June 1997, see abstract and Figures 1, 4 & 5.	1-3, 5-15, 18-24, 26, 28, 29, 31-35, 38-41
X	US 5,281,198 A (HABER et al.) 25 January 1994, see abstract and Figures 3-6.	1-3, 5-15, 18-24, 26, 28, 29, 31-35, 38-41
X	US 5,531,683 A (KRIESEL et al.) 02 July 1996, see Figure 25.	40 & 41.

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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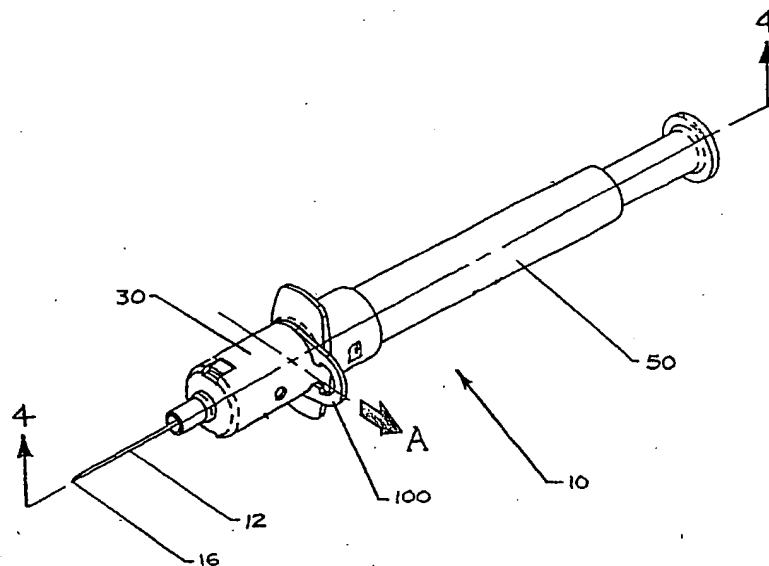
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PRE-FILLED SAFETY DILUENT INJECTOR

PRIORITY CLAIM

This application claims priority to U.S. Provisional Application No. 60/275,568, filed March 13, 2001, which is hereby incorporated herein by reference.

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FIELD OF THE INVENTION

The present invention relates to medical devices and more particularly to medical devices having a cartridge with two chambers that store separate components of a medication and allow the components to be mixed and subsequently injected into a patient.

BACKGROUND

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Pre-filled syringes store and allow for mixing of separate medicinal components. Many of these syringes, sometimes called "mixing syringes," store a first component in one compartment and a diluent or a second component in a second compartment. These syringes allow the two components to be stored separately until just before the syringe is used, at which time the components can be mixed within the syringe and immediately injected into a patient.

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Pre-filled mixing syringes are advantageous for many types of pharmaceuticals. Some medications, like antibiotics, vitamins and hormones, must be packaged and stored in component parts to enhance shelf life. These medications may need to be stored as a powdered component and a diluent, or as a separate pair of solutions. Pre-filled mixing syringes allow medications to be stored in component parts right up until the medication is

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injected. In addition, pre-filled mixing syringes eliminate the burden of measuring medicinal components and mixing diluents from separate containers.

5 Despite these advantages, prior mixing syringes have not offered reliable safety features to protect the syringe user from accidental needle sticks following injection. In particular, prior syringe assemblies have not provided a mixing syringe that operates integrally with an injection needle that can be automatically shielded upon completion of the injection.

10 SUMMARY OF THE INVENTION

With the foregoing in mind, the present invention provides a pre-filled medical device for mixing separate components of a medication and injecting the medication into a patient. The device includes a two-chambered
15 container, such as a cartridge, connected to a needle that retracts automatically after use. After retraction, the contaminated needle tip is enclosed within the device to prevent inadvertent needle sticks.

The device includes a hollow barrel surrounding the needle and
20 having a generally open rearward end that forms a socket. A two-chambered cartridge containing component parts of a medication is adapted to engage the socket. Prior to use, the components are stored separately in the two cartridge chambers. During use, a plunger disposed in the rearward end of the cartridge is advanced into the cartridge to combine the two components in
25 one chamber for mixing. Subsequent pressure on the plunger advances the medicinal mixture through the needle into a patient.

The injection needle is operable between an extended position and a retracted position. In the extended position, the forward tip of the
30 needle projects forwardly from the barrel. In the retracted position, the forward tip is enclosed within the barrel. When the needle is in the extended

position, a biasing element biases the needle toward the retracted position. A
needle retainer releasably retains the needle in the extended position against
the force of the biasing element. During the injection stroke, the cartridge
disengages the needle retainer to allow the biasing element to propel the
5 needle rearwardly into the barrel.

DESCRIPTION OF THE DRAWINGS

The foregoing summary as well as the following detailed
10 description of the preferred embodiments will be best understood when read
in conjunction with the following drawings, in which:

Fig. 1 is perspective view of a pre-filled cartridge injector having a two-
chambered container that stores component parts of a medication;

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Fig. 2 is an exploded perspective view of the cartridge injector shown in
Fig. 1;

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Fig. 3 is an enlarged view of a locking clip of the cartridge injector shown in
Fig. 2;

Fig. 4 is a sectional view of the cartridge injector shown in Fig. 1 taken along
the line 4-4;

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Fig. 5 is a sectional view of the cartridge injector shown in Fig. 4 taken along
the line 5-5;

Fig. 6 is a sectional view of the cartridge injector shown in Fig. 1, illustrating
the device prior to mixing the component parts of the medication;

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Fig. 7 is a sectional view of the cartridge injector shown in Fig. 1, illustrating

the device after mixing with the cartridge locked to impede injection;

Fig. 8 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device after mixing the cartridge unlocked to allow injection;

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Fig. 9 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device, after injection, just prior to needle retraction;

Fig. 10 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device after needle retraction.

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Fig. 11 is an enlarged fragmentary sectional view of the cartridge injector shown in Fig. 1, illustrating the tamper resistant connection between the cartridge and barrel after the needle is retracted.

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Fig. 12 is a sectional view of a second embodiment of a two-chambered pre-filled cartridge injector having a retractable needle.

Fig. 13 is a sectional view of the device shown in Fig. 12 taken along the line 13-13.

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Fig. 14 is a sectional view of the device shown in Fig. 12 illustrating the device during mixture of the medicinal components in the cartridge transfer of one component of medicine between chambers.

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Fig. 15 is a sectional view of the device shown in Fig. 12 illustrating the device after mixture of the medicinal components.

Fig. 16 is a sectional view of the device shown in Fig. 12 illustrating the device after needle retraction.

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Fig. 17 is a sectional view of a third embodiment of a two-chambered pre-filled cartridge injector having a retractable needle.

5 Fig. 18 is a sectional view of the cartridge portion of the device illustrated in Fig. 17.

Fig. 19 is a sectional view of the device shown in Fig. 17 illustrated without the cartridge, illustrated prior to use.

10 Fig. 20 is a sectional view of the cartridge in Fig. 18 illustrating the device during mixture of the medical components.

Fig. 21 is a sectional view of the device shown in Fig. 18 illustrating the device after mixture of the medical components.

15 Fig. 22 is a sectional view of the device shown in Fig. 17 illustrating the device at the completion of an injection.

20 Fig. 23 is a sectional view of the device shown in Fig. 17 illustrating the device after needle retraction.

Fig. 24 is an exploded perspective view of a fourth embodiment of a two-chambered pre-filled cartridge injector having a retractable needle.

25 Fig. 25 is a sectional view of the device illustrated in Fig. 24.

Fig. 26 is a sectional view of the device in Fig. 24 illustrating the device after mixture of the medical components.

30 Fig. 27 is a sectional view of the device shown in Fig. 24 illustrating the device at the completion of an injection.

Fig. 28 is a sectional view of the device shown in Fig. 24 illustrating the device after needle retraction.

5 Fig. 29 is a sectional view of the device shown in Fig. 24 illustrating the device after needle retraction.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the figures in general, and to Figs. 1-11 specifically, an injector device **10** is shown with a needle **12** having a sharpened distal tip **16** for insertion into a patient. As shown in Fig. 4, the injector device **10** has an attached cartridge **50** having a first chamber **52** and a second chamber **56**. The two chambers **52, 56** are pre-filled with component parts of a medication that are to be mixed prior to injection. The cartridge **50** also includes a plunger **40** that is slidable within the cartridge. Initially, advancing the plunger **40** in the cartridge **50** expels the medicinal component from the first chamber **52** into the second chamber **56** to mix the two medicinal components. After mixing the components, advancing the plunger drives the cartridge forwardly to inject the medicine into a patient. Upon completion of the injection stroke, the medical professional releases pressure from the plunger to allow automatic retraction of the needle **12** into the device **10** to protect the contaminated needle **12** from inadvertent contact.

The injector device **10** includes a double-ended needle **12**, a generally cylindrical barrel **30**, a compression spring **26** and a needle retainer **20** releasably retaining the needle against the bias of the spring. As shown in Figs. 4 and 5, the needle **12** has a sharpened proximal tip **14** and a sharpened distal tip **16**. The spring **26** circumscribes the needle **12** and is compressed against the interior of the barrel **30** at the barrel's distal end. The rearward end of the spring **26** bears against the interior of the needle retainer **20** to bias the needle **12** and needle retainer in the rearward direction.

The needle 12 is operable between two positions, an extended position and a retracted position. In the extended position, the needle 12 projects forwardly from the forward end of the barrel 30. In the retracted position, the needle 12 is retracted into the barrel 30 so that the sharpened tip 16 of needle 12 is enclosed within the barrel to prevent inadvertent contact with the sharpened tip. When the needle is in the extended position, the spring 26 biases the needle 12 rearwardly toward the retracted position. The needle retainer 20 releasably retains the needle 12 in the extended position, against the bias of the spring 26. During the injection stroke, the cartridge 50 cooperates with the needle retainer 20 to allow the needle to retract into the barrel 30, as shown in Fig. 10.

Referring now to Figs. 5-7, the cartridge 50 includes a first chamber 52 containing a first medicinal component 54 and a second chamber 56 containing a second medicinal component 58. The chambers 52, 56 are separated by a mid wall 60 containing an orifice 62. A rear seal 70 seals the first chamber 52 to prevent the components from being mixed prior to use. When the rear seal 70 is pierced and the plunger 40 is advanced into the cartridge 50, the first component 54 flows into the second chamber 56 through the orifice 62, where it combines with the second component 58 to form the medication 59, as shown in Figs. 6-7. Subsequent pressure on the plunger 40 and cartridge 50 forces the medication 59 through the needle 12 and into the patient.

Referring now to Figs. 4-6, the elements of the injector device 10 will be described in greater detail. The barrel 30 is generally cylindrical and the distal end of the barrel has a tapered nose 32. The nose 32 has an opening through which the needle 12 extends so that the sharpened tip 16 of the needle can be inserted into a patient. The rearward end of the barrel 30 is open, forming a cylindrical socket 34 adapted to receive the cartridge 50. Two laterally extending flanges 36 project outwardly from the barrel 30,

transverse the longitudinal axis of the barrel, forming a pair of finger grips for operating the device 10. The barrel 30 further includes a pair of retaining apertures 38 and a pair of lockout windows 39 that cooperate with the needle retainer 20 as described further below.

5

As shown in Fig. 5, a hub 21 projects from the rearward end of the needle retainer 20. The hub 21 is a generally cylindrical element having a central bore 23. The needle 12 is disposed within the central bore 23 of the hub 21 so that the rearward end 14 of the needle 12 projects rearwardly from the hub and the forward end 16 of the needle projects forwardly from the hub. The needle 12 can be attached to the hub 21 in one of several ways. For example, the needle 12 can be attached to the hub 21 by an adhesive such as a UV curable adhesive. Alternatively, the needle 12 can be molded into the hub 21, which is formed of plastic. The rearward end of the hub 21 includes a circumferentially barbed connector 25 configured to cooperate with the cartridge 50 to connect the cartridge to the needle hub 21 as discussed further below.

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The needle retainer 20 is axially displaceable within barrel 30 to facilitate needle retraction. The needle retainer 20 can be molded out of a rigid, high strength resin, such as polycarbonate. Prior to retraction, the needle retainer 20 is maintained in a fixed axial position while the medication 59 is expelled from the cartridge 50. After the injection, the needle retainer 20 and the attached needle 12 are displaced rearwardly by the compression spring 26.

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The spring 26 is a compression spring and may be formed of stainless steel, treated carbon steel wire or other suitable non-corrosive spring metal. The residual compression of the spring prior to disengagement of the needle retainer is of sufficient magnitude to facilitate complete needle retraction and overcome the frictional resistance between sliding components within the device 10.

Referring now to Fig. 6, the needle retainer **20** includes a pair of retaining arms **22** that extend radially outwardly and forwardly from the distal end of the needle retainer **20**. During operation, the needle retainer **20** is operable between a locked position and an unlocked position. In the locked position, the retaining arms **22** engage the retaining apertures **38** in the barrel wall to maintain the needle in a fixed axial position with the forward tip **16** of needle **12** projecting forwardly from the barrel **30**. More specifically, in the locked position, the retaining arms **22** engage the barrel **30** to hold the needle hub **21** and needle **12** against the rearward bias of the spring **26**. In the unlocked position, the retaining arms **22** are positioned so as to allow the needle hub **21** and needle **12** to be retracted rearwardly. More specifically, in the unlocked position, the retaining arms **22** are disengaged from the retaining apertures **38**, allowing the spring **26** to propel the needle hub **21** and needle **12** rearwardly.

As discussed above, the retaining arms **22** on the needle retainer **20** project forwardly and outwardly into engagement with the retaining apertures **38** in the wall of the barrel **30**. The terminal end of each arm forms a retaining tab **24** that is configured to project into a retaining aperture **38**. More specifically, the retaining tabs **24** engage the lip formed by each retaining aperture **38** in the wall of the barrel **30**. In this way, the retaining tabs **24** operate as a pair of latches to retain the needle hub **21** and needle **12** against the rearward bias of the spring.

Referring again to Figs. 4 and 5, the cartridge **50** is a generally cylindrical vessel that may be molded out of pharmaceutical quality glass such as borosilicate, or a rigid inert plastic such as polyolefin or polyester. The midwall **60** that separates the first and second chambers may be formed of a rigid inert plastic such as polyolefin or polyester. The barrier or midwall **60** can be molded as part of the cartridge **50** or bonded to the inside wall of the cartridge. Each chamber is filled with a predetermined amount of a

medication during manufacturing of the device 10.

The front end of the forward chamber 56 is sealed by an elastomeric front seal 80, which may be molded in a self-sealing biocompatible elastomer such as polyisoprene. The front seal 80 is generally cylindrical, having a plurality of axially-spaced circumferential ribs 81. The ribs 81, which are more clearly shown in Fig. 2, frictionally and sealingly engage the interior of the container to provide a fluid tight seal, thereby preventing fluid from leaking from the cartridge 50. The front seal 80 also has a front end that is pierceable by the rearward sharpened tip 14 of needle 12. After being pierced, the front end of the front seal 80 reseals around the needle 12 to prevent fluid from leaking from the cartridge 50.

Referring now to Figs. 5 and 6, the front seal 80 has a socket 82 configured to cooperate with the barbed connector 25 on the needle hub 21. The socket 82 includes two radially relieved recesses, 82a and 82b, that mate with the barbed connector 25. Specifically, the barbed connector 25 matingly engages the front seal 80 in a first position and a second position.

In the first position, the barbed connector 25 engages the first recess 82a, as shown in Fig. 5. In this position, the cartridge is attached to the hub, but the rearward end of the needle does not pierce the front seal 80. Applying pressure to the plunger 40 displaces the cartridge forwardly relative to the hub, thereby displacing the barb into the second position. In the second position, the barbed connector 25 engages the second recess 82b, as shown in Fig. 6. In this position, the rearward end of the needle 12 pierces the front seal 80.

The front seal 80 includes a hollowed cavity 84 at its rearward end. In this way, a pierceable wall 86 is formed in the front seal 80 between the cavity 84 and the second recess 82b. As shown in Fig. 5 prior to use, the

cartridge 50 is mounted in the first position so that the barbed connector 25 engages the first recess 82a. In this position, the needle 12 does not penetrate the pierceable wall 86. As the hub 21 is displaced from the first position to the second position, the rearward end 14 of the needle 12 pierces the wall 86 and extends into the cavity 84 as shown in Fig. 6. The cavity 84 opens into the interior of the second chamber 56 of cartridge 50 so that when the needle 12 projects into the hollowed section 84, the needle is in fluid communication with the interior of the cartridge. After the needle 12 penetrates the pierceable wall 86, the wall reseals around the needle to form a fluid-tight seal and prevent medication in the cartridge 50 from leaking around the needle.

To prepare the injection device 10 for use, the medical professional displaces the cartridge 50 forwardly relative to the needle retainer 20, so that the forward seal 80 is driven over the barbed connector 25, such that the barbed connector engages the second recess 82b. At the same time, the proximal tip 14 of needle 12 pierces the pierceable wall 86, so that the needle is in fluid communication with the second chamber, as shown in Fig. 6.

The connection between the front seal 80 and the needle hub 21 is preferably a one-way engagement. In other words, when the front seal 80 is mounted on the barbed connector 25, the cartridge 50 can be displaced forwardly relative to the barbed connector, but the cartridge cannot be displaced rearwardly relative to the barbed connector. In this way, the cartridge 50 cannot be readily removed from the needle hub 21 in barrel 30, such that the cartridge is substantially permanently attached to the needle hub and barrel.

The one-way connection is facilitated by the rearward-facing tapered shoulder of the barbed connector 25 and the square shaped forward-

facing shoulder of the barbed connector. In particular, the rearward-facing shoulder of the barbed connector **25** cooperates with tapered sides in the first and second radial recesses **82a** and **82b** to permit relative displacement of the plug from the first recess to the second recess. Reverse displacement
5 from the second recess **82b** back to the first recess **82a** is resisted by the square shaped forward-facing shoulders on barbed connector **25**, which act to impede reverse displacement.

Referring now to Fig. 4, the front seal **80** is configured to
10 prevent ejection of fluid when the barbed connector **25** is displaced from the first position, in which the barbed connector **25** engages the first radial recess **82a**, to the second position, in which the barbed connector engages the second radial recess **82b**. Specifically, the front seal **80** includes a flared
15 head **88** or circumferential flange at the forward end of the front seal. The open distal end of the cartridge **50** terminates with a beaded rim **51** that seats against the rearward edge of the flared head **88**. The outside diameter of the flared head **88** is greater than the inside diameter of the open distal end of the cartridge **50**, thereby impeding rearward displacement of the front seal **80** into
20 the cartridge when force is initially applied to the plunger **40**. In addition, the force required to overcome the frictional engagement between the outer circumference of the front seal **80** and the inner wall of the cartridge **50** is greater than the force required to displace the plug **25** from the first recess **82a** to the second recess **82b**. Accordingly, when force is initially applied to
25 the plunger **40**, the front seal **80** remains in a fixed position relative to the cartridge **50**, while the barbed connector **25** is displaced into the second position. This restriction on the front seal **80** limits the release of fluid from the cartridge **50** when the needle **12** pierces the wall **86**.

During storage of the injection device **10**, the medication is
30 divided into two separate components stored in the cartridge **50**, as shown in Fig. 5. Specifically, a first component **54** of the medicine is stored in the rear

chamber 52 and a second component 58 of the medicine is stored in the forward chamber 56. The two chambers are separated by the mid-wall 60 containing an orifice 62 and a hollow piercing member 64 mounted in the orifice. The orifice 62 is located axially at the center of the midwall 60. In addition, a small vent hole 63 is located just off center in the midwall 60 to vent the air from the dead space area between the mid wall and the mid seal 70. Preferably, the piercing member 64 is fabricated out of suitable non-corrosive material such as stainless steel or treated carbon steel wire. When the plunger 40 is axially advanced in the cartridge 50, the first component 54 in the rear chamber 52 advances through the piercing member 64 and into the forward chamber 56 to combine with the second component 58.

Prior to use of the injection device 10, fluid communication between the first and second chambers is prevented by an elastomeric mid seal 70, which may be molded in a self-sealing biocompatible elastomer such as polyisoprene. The mid seal 70 is initially slidably disposed in the first chamber 52 between the piercing member 64 and the first component 54, as shown in Figs. 4-5. The mid seal 70 is generally cylindrical, having a plurality of axially-spaced circumferential ribs 71, as shown more clearly in Fig. 2. The ribs 71 frictionally and sealingly engage the inner wall of the cartridge 50 to provide a fluid-tight seal. This fluid-tight seal prevents fluid in the first chamber from entering the piercing member 64. The mid seal 70 also includes a hollowed section 72 formed in the forward end of the mid seal that opens to the first chamber 52 at the rearward end of the mid seal. The forward end of the mid seal 70 is closed by a membrane 78 that is pierceable by the piercing member 64. Upon piercing the membrane 78, fluid communication is established between the first and second chambers to allow the first and second components of the medication to be mixed.

Like the front seal 80 and mid seal 70, the plunger 40 is generally cylindrical, preferably having a plurality of axially-spaced

circumferential ribs 41. The plunger 40 may be molded in a self-sealing biocompatible elastomer such as polyisoprene. Alternatively, the plunger 40 could be a two-part assembly in which a cylindrical elastomeric seal is mounted to a rigid plastic plunger rod. The ribs 41, which are more clearly shown in Fig. 2, frictionally and sealingly engage the interior of the cartridge 50 to provide a fluid tight seal, thereby preventing fluid from leaking from the proximal end of the cartridge.

The plunger 40 is slidable within the first chamber 52 in response to pressure applied to the thumb pad 42. When the plunger 40 is axially advanced into the cartridge 50, the first component 54 is compressed against the rearward end of the mid seal 70 in the first chamber 52. As back pressure on the mid seal 70 overcomes the frictional resistance between the mid seal and the cartridge 50, the mid seal is displaced into the piercing member 64 until the membrane 78 is pierced, as shown in Fig. 6. As the mid seal advances, air from the space between the mid seal and mid wall vents through the vent hole 63 in the mid wall. At such time, the piercing member 64 penetrates through the hollowed section 72 to connect the first chamber 52 and second chamber 56 in fluid communication.

After the mid seal 70 is pierced, pressure applied to the plunger 40 advances the first component 54 through the piercing member 64 and into the second chamber 56 where the first and second components are subsequently mixed to form the medication 59. The plunger 40 is displaced forwardly relative to the first chamber 52 until the flanged portion of the thumb pad 42 contacts the proximal end of the cartridge 50, as shown in Fig. 7. The outside diameter of the thumb pad 42 is larger than the inside diameter of the cartridge 50, thereby preventing further displacement of the plunger 40 once the thumb pad contacts the proximal end of the cartridge 50. Preferably, the distance between the forward end of the plunger 40 and the rearward end of the mid seal 70 is equal to the distance between the flanged portion of the

circumferential ribs 41. The plunger 40 may be molded in a self-sealing biocompatible elastomer such as polyisoprene. Alternatively, the plunger 40 could be a two-part assembly in which a cylindrical elastomeric seal is mounted to a rigid plastic plunger rod. The ribs 41, which are more clearly shown in Fig. 2, frictionally and sealingly engage the interior of the cartridge 50 to provide a fluid tight seal, thereby preventing fluid from leaking from the proximal end of the cartridge.

The plunger 40 is slidable within the first chamber 52 in response to pressure applied to the thumb pad 42. When the plunger 40 is axially advanced into the cartridge 50, the first component 54 is compressed against the rearward end of the mid seal 70 in the first chamber 52. As back pressure on the mid seal 70 overcomes the frictional resistance between the mid seal and the cartridge 50, the mid seal is displaced into the piercing member 64 until the membrane 78 is pierced, as shown in Fig. 6. As the mid seal advances, air from the space between the mid seal and mid wall vents through the vent hole 63 in the mid wall. At such time, the piercing member 64 penetrates through the hollowed section 72 to connect the first chamber 52 and second chamber 56 in fluid communication.

After the mid seal 70 is pierced, pressure applied to the plunger 40 advances the first component 54 through the piercing member 64 and into the second chamber 56 where the first and second components are subsequently mixed to form the medication 59. The plunger 40 is displaced forwardly relative to the first chamber 52 until the flanged portion of the thumb pad 42 contacts the proximal end of the cartridge 50, as shown in Fig. 7. The outside diameter of the thumb pad 42 is larger than the inside diameter of the cartridge 50, thereby preventing further displacement of the plunger 40 once the thumb pad contacts the proximal end of the cartridge 50. Preferably, the distance between the forward end of the plunger 40 and the rearward end of the mid seal 70 is equal to the distance between the flanged portion of the

thumb pad 42 and the proximal end of the cartridge 50. Once the thumb pad 42 contacts the proximal end of the cartridge 50, the plunger is fixed relative to the cartridge 50. At this point, axial advancement of the cartridge 50 relative to the barrel 30 is restricted, as described in more detail below.

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Preferably, the injection device 10 includes a locking mechanism for preventing accidental release of the contents in the second chamber prior to mixing the two components. In the present embodiment shown in Fig. 7, the barrel 30 includes a locking clip 100 in the barrel wall to prevent accidental discharge of the medicinal components. The wall of the barrel 30 includes a pair of radial slots 104 formed in a plane that is transverse the longitudinal axis of the barrel. When the locking clip 100 is inserted through the slots 104, the clip prevents inadvertent forward displacement of the cartridge 50 relative to the front seal 80, thereby preventing accidental advancement of the medicinal components through the needle 12. The locking clip 100 is preferably formed of a resilient high strength and high modulus resin, such as acetyl or polycarbonate, and is configured to releasably engage the slots 104 in the barrel 30.

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Referring to Figs. 1-3, the locking clip 100 is preferably a flat member having a pair of resiliently deflectable legs 101 that join to form a U-shape. The open end of the locking clip 100 has tapered edges 102 that allow the legs 101 to deflect outwardly as the locking clip 100 is inserted into the sidewall of the barrel 30. In addition, the locking clip 100 has a plurality of teeth 103 on the inside edge of the legs 101 that are adapted to engage the edges of radial slots 104.

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As the locking clip is inserted into the sidewall of the barrel 30, the legs 101 deflect outwardly to allow the teeth 103 to clear the edges of radial slots 104. Upon being deflected outwardly, the resilience of legs 101 bias the legs radially inwardly toward their original position. Once the teeth

103 are disposed within the slots 104, the legs 101 deflect radially inwardly toward their original position and releasably engage the outer edges of the needle retainer 20 in barrel 30. In the inserted position, the closed end of the locking clip 100 remains outside the barrel 30, as shown in Figs. 1 and 4.

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After the medicinal components are mixed within the cartridge, the locking clip 100 is removed to permit injection of the medicine 59, as shown in Fig. 8. The locking clip 100 is removed from the barrel 30 by pulling
10 the closed end of the clip in a direction transverse to the longitudinal axis of the barrel. This direction is marked "A" in Fig. 1. By pulling the clip in this manner, the legs 101 are deflected outwardly from the slots 104 to allow the teeth 103 to clear the edges of slots 104.

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After the locking clip 100 is removed from the barrel 30, the medication 59 is injected into the patient by advancing the cartridge forwardly into the barrel. Pressure applied to the thumb pad 42 causes the plunger 40 and cartridge 50 to move forwardly relative to the barrel 30. With the barbed connector 25 mounted in the second recess 82b in the front seal 80, the front
20 seal remains stationary while the cartridge 50 is advanced forwardly, as shown in Fig. 9. The front seal 80 and flared head 88 are configured to form a sliding fit with the interior of the cartridge 50 so that the cartridge can slide over the front seal. As the cartridge 50 is advanced, the mid seal 70 and the mid wall 60 are displaced toward the front seal 80. This causes a reduction of
25 volume in the second chamber 56, whereby the medication is displaced into the needle to facilitate the injection. At the completion of the injection, the mid wall 60 bears against the rearward end of the front seal 80, as shown in Fig. 9.

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Referring now to Figs. 9-10, the automatic retraction of the needle 12 shall be described. The cartridge 50 is axially advanced to the

proximal end of the barrel **30** until the medication **59** is completely expelled from the second chamber **56**. As the cartridge **50** is advanced, the beaded circumferential rim **51** of the cartridge is displaced into engagement with the retaining arms **22** of needle retainer **20**. Preferably, the cartridge **50** is configured so that the longitudinal distance between the rearward end of the front seal **80** and the mid wall **60** corresponds to the longitudinal distance between the circumferential rim **51** of the cartridge and the retaining arms **22** when the cartridge is mounted on the barbed connector **25** in the second position. In this way, the rim **51** of the cartridge **50** engages the retaining arms **22** when substantially all of the medication **59** is expelled from the device **10**.

After the rim **51** of cartridge **50** engages the retaining arms **22**, continued axial advancement of the cartridge deflects the retaining arms radially inwardly so that the retaining tabs **24** are displaced inwardly, as shown in Fig. 9. In the inward position, the retaining tabs **24** are disengaged from the retaining apertures **38** of the barrel **30**. In this way, the cartridge **50** operates as an actuator, such that axial advancement of the cartridge displaces the needle retainer **20** into an unlocked position. In the unlocked position, the needle retainer **20** is no longer locked in place against the force of the spring **26**. After the needle retainer **20** is in the unlocked position and the user releases pressure on the plunger **40**, the spring **26** propels the needle **12** rearwardly until the sharpened distal tip **16** of the needle is enclosed within the barrel **30**.

As shown in Fig. 10, when the needle **12** is retracted, the needle, needle retainer **20** and cartridge **50** are displaced rearwardly together. During retraction, the retaining arms **22** are biased radially outwardly so that the retaining tabs **24** ride along the inside wall of the barrel. The force of the spring **26** is sufficiently strong to overcome the frictional resistance generated between the guide arms **28** and the barrel **30**.

Preferably, the injection device 10 includes a mechanism for limiting rearward displacement of the retracted elements. Referring now to Figs. 2, 4 and 10, the needle retainer 20 includes a pair of guide arms 28 that cooperate with a pair of alignment channels or grooves 31 formed in the interior wall of the barrel 30. The guide arms 28 may be molded out of a rigid, resilient high strength resin, such as polycarbonate. The guide arms 28 extend forwardly from the needle retainer 20 and project radially outwardly into engagement with the alignment grooves 31.

Each guide arm 28 includes a linear elongated rear portion which preferably is generally parallel to the longitudinal axis of barrel 30. The forward portion of each guide arm 28 bends outwardly transverse to the longitudinal axis of the barrel 30 and extends into one of the alignment grooves 31. When the needle retainer 20 is disposed within the barrel, the guide arms 28 are deflected radially inwardly from their natural state. In this position, the guide arms 28 are biased radially outwardly against the inner wall of the barrel 30 due to the resilient properties of the guide arms.

The forward ends of guide arms 28 are preferably contained within the alignment grooves 31 to substantially limit rotation of the needle and needle retainer 20 during needle retraction. This engagement ensures that the guide arms are aligned with the lockout windows 39 so that the guide arms snap into the lockout windows at the end of retraction. In this way, the needle retainer 20 is limited to axial displacement during needle retraction. During retraction, the frictional resistance between the forward ends of the guide arms 28 and the inside wall of the barrel 30 is overcome by the expansion force of the spring 26.

As shown in Fig. 4, the linear elongated rear portion of each guide arm 28 is spaced radially inwardly from the inner wall of the barrel 30 to create a clearance space between the linear portion of the guide arms and

the barrel. Preferably, the minimum radial thickness of the clearance space is greater than the thickness of the wall of the cartridge 50 or the cartridge rim 51. In this way, when the cartridge 50 is advanced forwardly to disengage the retaining arms 22, advancement of the cartridge will not be impeded by the guide arms 28.

Each alignment groove 31 is substantially parallel to the longitudinal axis of the barrel 30. In Fig. 4, the groove 31 is shown extending to rearward end of the barrel. However, it may be desirable to terminate the groove forward of the rearward end of the barrel. The rearward portion of each alignment groove 31 intersects a lockout window 39 formed in the wall of the barrel 30. The lockout windows 39 are adapted to receive the forward ends of the guide arms 28, as shown in Fig. 10. In particular, as the front end of each guide arm 28 aligns with the corresponding lockout window 39 during needle retraction, the radially outward bias of the guide arm displaces the arm outwardly so that the forward end projects into the lockout window. The engagement between the guide arms 28 and lockout windows 39 prevent further axial movement of the retainer 22. As a result, the retracted elements are limited from further displacement in the forward or rearward direction.

Preferably, the injection device 10 includes a mechanism to limit tampering or removal of the cartridge 50 from the barrel socket 34. Referring now to Fig. 11, the present embodiment includes an annular lip 35 that projects radially inwardly from the inside wall of the socket 34 in barrel 30. The lip 35 is adapted to seat against the beaded rim 51 on the cartridge 50 so that the cartridge can not be easily pulled out of the rear of the barrel 30. As a result, access to the retracted elements, and the contaminated needle in particular, is limited.

Referring now to Figs. 4-10, the operation of the injection device

10 will be described. Prior to use, the needle 12 is disposed in an extended position so that the distal end 16 of the needle projects forwardly from the barrel 30, as shown in Fig. 4. Preferably, the device 10 is shipped with the cartridge 50 already mounted in barrel 30 so that the barbed connector 25 is engaged in the first recess 82a. Alternatively, the cartridge 50 may be shipped separately from the barrel 30, so that the cartridge must be attached to the barrel prior to use.

With the cartridge 50 and barrel 30 assembled, the device 10 is held vertically so that the distal end 16 of needle 12 points upwardwardly. The user holds the device 10 by placing the user's thumb in a supporting position beneath the thumb pad 42 of plunger 40. In addition, the user places a finger over each finger grip 36 to control the operation of the device 10. With the user's fingers anchored over the finger grips 36, the user applies a slight squeezing pressure on the thumb pad 42, much like a conventional syringe. The squeezing pressure displaces the cartridge 50 forwardly relative to the barrel so that the barbed connector 25 on the needle retainer 20 engages the second recess 82b in front seal 80 and the needle 12 pierces the wall 86. As the front seal 80 is pierced, entrapped air in the forward chamber 56 is vented through needle 12.

Continued advancement of the plunger 40 drives the seal 70 toward the piercing element 64 until the piercing element pierces the mid seal, thereby providing fluid communication between the forward and rearward chambers 52, 56. At this point, the first component 54 may be advanced into the forward chamber 56. Pressure is applied on the thumb pad 42 until the first component 54 is completely expelled from the rearward chamber 52 into the forward chamber 56 and the forward end of the plunger meets the rearward end of the mid seal 70. The user then shakes the injector device 10 to mix the first and second components 54, 58 inside the forward chamber 56.

During mixing, the locking clip **100** prevents the cartridge **50** from being advanced forwardly into the needle retainer **20**. This constraint on the cartridge **50** limits the potential for inadvertent discharge of the medication **59** from the needle **12** and premature needle retraction. Once the medication **59** is adequately mixed, the user removes the locking clip **100** from the barrel **30** so that the cartridge **50** can be advanced forwardly within the barrel. At this point, initial pressure applied to the thumb pad **42** advances the cartridge and vents excess air out of the second chamber **56**.

The needle is then inserted into a patient and the plunger **40** is depressed to axially advance the cartridge **50** relative to the barrel **30**, thereby injecting the medication **59** from the cartridge into the patient. At the end of the injection stroke, the beaded rim **51** on the cartridge **50** engages the retaining arms **22**, thereby displacing the retaining tabs **24** radially inwardly to disengage the needle retainer **20** into the unlocked position. Although the needle retainer **22** is in the unlocked position, the needle **12** does not retract until the user releases pressure from the thumb pad **42**. In this way, the user can retain pressure on the thumb pad **42** until after the needle is withdrawn from the patient. The user can then release pressure from the thumb pad **42** so that the needle is propelled rearwardly by the spring **26**. Alternatively, the user can release pressure from the thumb pad **42** while the needle **12** is still inserted in the patient. Once the thumb pad **42** is released, the spring **26** propels the needle **12** rearwardly so that the contaminated distal tip **16** of the needle is enclosed within the barrel **30**.

Referring now to Figs. 12-16 in general, and to Figs. 12-13 specifically, a second embodiment of a pre-filled safety diluent injector is shown. The injector device **110** includes elements that are substantially similar to the elements described above in connection with the first embodiment 10, illustrated in Figs. 1-11. These elements include: a double-ended needle **112**, a generally cylindrical barrel **130**, a compression spring

126, a needle retainer 120 releasably retaining the needle against the bias of the spring, a locking clip 200. The needle 112 has a sharpened proximal tip 114 and a sharpened distal tip 116. The spring 126 circumscribes the needle 112 and is compressed against the interior of the barrel 130 at the barrel's forward end. The rearward end of the spring 126 bears against the interior of the needle retainer 120 to bias the needle 112 and needle retainer in the rearward direction.

In contrast to the previous embodiment, the second embodiment utilizes a cartridge 150 having a selectively sealable by-pass fluid passage 160 to separate the two medicinal components, rather than a mid wall and a pierceable seal as described above with the first embodiment. Prior to use, a mid seal 170 within the cartridge 150 separates the two medicinal components 154, 158. Prior to use, the mid seal 170 is displaced forwardly adjacent the by-pass passage 160, which provides a fluid passage, allowing the two medicinal components 154, 158 to be mixed. The mixed components can then be injected into the patient.

Referring to Figs. 12, 13, the detail of the Cartridge 150 will be described in greater detail. The cartridge is a generally cylindrical container. The forward end of the cartridge is sealed by the pierceable forward seal 180. The rearward end of the cartridge is sealed by a piston 143 that forms a fluid-tight seal with the interior wall of the cartridge. Intermediate the forward seal 180 and the piston 143, a mid seal 170 forms a fluid-tight seal with the interior wall of the cartridge, separating the cartridge into two chambers, a forward chamber 156 for receiving a first component 158, and a rearward chamber 152 for receiving a second component 154.

The cartridge 150 includes a bubble-like fluid passage 160 that protrudes outwardly from the side of the cartridge. The fluid passage 160 forms an area in which the diameter of the cartridge is greater than the

diameter of the mid seal. The fluid passage **160** is an axially elongated channel having a length that is greater than the axial length of the mid seal **170**, and preferably, is shorter than the combined length of the mid seal and the piston **143**.

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Although the fluid passage **160** is illustrated as a bubble-like protrusion, the fluid passage may be formed in other configurations. For instance, the fluid passage may be a recess or axial groove formed in the interior wall of the cartridge **150**, so that the fluid passage does not protrude from the exterior surface of the cartridge. Similarly, the fluid passage may be an annular recess formed in the interior wall of the cartridge.

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Referring to Fig. 12, the device **110** is illustrated in a "storage" position. In this position, the mid seal **170** prevents the two medicinal components from mixing. Therefore, the sealed cartridge **150** can be stored for an extended period, if desired, without compromising the efficacy of the medicinal components. In the stored position, the mid seal **170** is disposed rearwardly of the fluid passage **160** so a fluid-tight seal is formed between the mid seal and the interior wall of the cartridge, around the entire circumference of the mid seal.

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During storage of the injection device **110**, the medication is divided into two separate components stored in the cartridge **150**, as shown in Figs. 12-13. Specifically, the first component **154** of the medicine is stored in the first chamber **152** and the second component **158** of the medicine is stored in the second chamber **156**. As discussed further below, preferably, when the cartridge is being filled during manufacture, a quantity of air remains within the second chamber **156**.

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A plunger **140** is slidably disposed in the rearward end of the cartridge **150**. The plunger **140** is comprised of a plastic molded plunger rod

141 and an elastomeric piston 143. The piston 143 forms a fluid-tight seal with the inner wall of the cartridge, and is slidably displaceable within the cartridge. The plunger rod 141 can be connected to the plunger seal 143 in a number of ways. In the present embodiment, the plunger rod 141 includes
5 external screw threads that are configured to engage internal threads inside the plunger seal 143, whereby the plunger rod and seal can be screwed together.

Referring now to Fig. 14, the transfer of the first medicine
10 component 154 into the second chamber 156 shall be described. The mid seal 170 is advanced axially until it registers with the fluid passage 160. The fluid passage 160 then provides a by-pass passage so that the component in the rearward chamber can be injected into the forward chamber. Since the forward chamber preferably includes a quantity of air (or other compressible
15 fluid), the material in the forward chamber can be compressed to allow the mid seal to be advanced into registry with the fluid passage 160. Alternatively, the forward chamber may include a vent for venting the air from the forward chamber when the fluid is transferred from the rearward chamber into the forward chamber. If a vent is included, preferably the vent is sealable
20 to prevent leakage of the mixed components during injection.

Specifically, to mix the two components in the cartridge, the plunger 140 is axially advanced into the cartridge 150, to compress the first component 154 against the rearward end of the mid seal 170 in the first
25 chamber 152. As back pressure on the mid seal 170 overcomes the frictional resistance between the mid seal and the cartridge 150, the mid seal is displaced forwardly in the cartridge. Once the mid seal 170 is displaced into alignment with the fluid passage 160, a passage is created between the mid seal and the inside wall of the fluid passage, as shown in Fig. 14.

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The fluid passage 160 is sufficiently large to allow the first

substance **154** to flow around the mid seal and into the second chamber **156** where it is mixed with the second substance **158**. Once the first component is completely transferred to the second chamber **156**, the plunger seal **143** is advanced until it abuts the mid seal **170**, as shown in Fig. 15. The combined
5 axial length of the mid seal **170** and piston **143** is slightly longer than the length of the fluid passage **160**. Therefore, the mid seal and piston seal off the entire length of the fluid passage. This prevents the contents of the second chamber **156** from backflowing during mixing of the components.

10 After mixing of the components is completed, the locking clip **200** is removed to allow injection of the medication into the patient. Pressure is applied to the cartridge **150** to discharge the medication from the second chamber **156**. At the completion of the injection stroke, the cartridge **150** actuates the needle retainer **120**. Pressure on the cartridge **150** is then
15 released so that the needle can be retracted, as shown in Fig. 16.

Referring now to Figs. 17-23 in general, and to Fig. 17 specifically, another embodiment of a pre-filled safety diluent injector is designated generally **210**. The injector device **210** includes a double-ended
20 needle **212**, a generally cylindrical barrel **230** that houses the needle and a generally cylindrical cartridge **250**. The barrel **230** further includes a compression spring **226** and a needle retainer **220** releasably retaining the needle **212** against the bias of the spring. The needle **212** has a sharpened rearward tip **214** and a sharpened forward tip **216**. The spring **226**
25 circumscribes the needle **212** and is compressed against the interior of the barrel **230** at the barrel's forward end. The rearward end of the spring **226** bears against the interior of the needle retainer **220** to bias the needle **212** and needle retainer in the rearward direction.

30 In this embodiment, the transferring and mixing of the medication components is done in the cartridge **250** prior to attaching the

cartridge to the needle hub 221. Since the cartridge **250** is not connected to the needle assembly during mixing, there is no risk of inadvertently retracting the needle during the mixture of the components. As a result, the barrel does not include a locking clip, as in the other embodiments.

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Referring now to Figs. 18-19, the cartridge **250** and barrel **230** are packaged and distributed so that the two are disassembled. The cartridge **250** is a generally cylindrical vessel that may be molded out of pharmaceutical quality glass such as borosilicate or a rigid inert plastic such as polyolefin or polyester. A cartridge cap **253** is disposed over the distal end of the cartridge **250**. The cartridge **250** is configured similar to the cartridge **150** illustrated in Figs. 12 - 16, and includes a bubble-like fluid passage **260** that protrudes outwardly from the side of the cartridge. A mid seal **270** is slidably disposed in the cartridge **250** and divides the cartridge into a first chamber **252** and a second chamber **256**. Each chamber of cartridge **250** is filled with a predetermined amount of a component of medication during manufacturing of the device **210**. In particular, the first chamber **252** is prefilled with a first component **254** of the medication and the second chamber **256** is prefilled with a second component **258**.

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Referring now to Fig. 20, a plunger **240** is slidably disposed in the proximal end of the cartridge **250**. The plunger **240** is comprised of a plastic molded plunger rod **241** and an elastomeric plunger seal **243**. When the plunger **240** is axially advanced into the cartridge **250**, the first component **254** is compressed against the rearward end of the mid seal **270** in the first chamber **252**. As back pressure on the mid seal **270** overcomes the frictional resistance between the mid seal and the cartridge **250**, the mid seal is displaced forwardly in the cartridge. Once the mid seal **270** is displaced into alignment with the fluid passage **260**, a passage is created between the mid seal and the inside wall of the fluid passage to allow the first substance **254** to flow around the mid seal and into the second chamber **256** where it is mixed

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with the second substance **258**.

The fluid passage **260** is sufficiently long to allow the first substance **254** to flow around the mid seal and into the second chamber **256** where it is mixed with the second substance **258**. Once the first component is completely transferred to the second chamber **256**, the plunger seal **243** is advanced until it abuts the mid seal **270**, as shown in Fig. 21. The combined axial length of the mid seal **270** and plunger seal **243** is slightly longer than the maximum length of the fluid passage **260** so that the mid seal and plunger seal close off the entire length of the fluid passage. This prevents the contents of the second chamber **256** from backflowing during mixing of the components.

Referring again to Fig. 18, the cartridge **250** includes an elastomeric front seal **280** in the distal end of the cartridge. The front seal **280** may be molded of a self-sealing biocompatible elastomer such as polyisoprene. The front seal **280** is generally cylindrical with a wide cylindrical rearward end **282** disposed within the cartridge and a reduced diameter forward end **284** projecting forwardly from the forward end of the cartridge. The rearward end **282** has an outside diameter that is similar to the inside diameter of the cartridge **250**. In addition, the rearward end **282** has a plurality of axially-spaced circumferential ribs **286** that frictionally and sealingly engage the interior of the cartridge to provide a fluid tight seal and prevent fluid from leaking from the cartridge.

The forward end **284** of front seal **280** includes an external thread **288** about its circumference. The distal end **284** also contains a shallow frontal cavity **290**. A narrow bore **292** in fluid connection with the second chamber **256** extends from the proximal end of the front seal **280** and terminates within the reduced diameter distal end **284**. Fluid communication between the frontal cavity **290** and the bore **292** is obstructed by a pierceable

membrane **294**.

Referring now to Fig. 19, the barrel **230** is generally cylindrical and has a tapered nose **232** at its distal end. The nose **232** has an opening through which the needle **212** extends. In addition, the nose **232** is configured to receive a needle cover **211** that fits over the nose to prevent accidental needle sticks when the needle **212** is in an extended position. The proximal end of the barrel **230** is open, forming a cylindrical socket **234** adapted to receive the cartridge **250**. Prior to attachment with the cartridge **250**, the rearward open end of the barrel **230** is closed by a cylindrical barrel cap **233**. The barrel further includes a pair of retaining apertures **238** that cooperate with the needle retainer **220** to releasably retain the needle, and a pair of lockout windows that cooperate with locking tabs to lock the needle in the retracted position.

The needle retainer **220** includes a generally cylindrical body **221** and a pair of retaining arms **222** that extend radially forwardly from the body **221**. A generally cylindrical aperture **296** is disposed within the proximal end of the needle retainer body **221**. The inner wall of the aperture **296** includes internal screw threads **298** that are adapted to receive the external screw thread **288** of the front seal **280** in the cartridge **250**.

The cartridge cap **253** and barrel cap **233** are removed from the cartridge **250** and barrel **230**, respectively, to prepare the cartridge and barrel for assembly. The cartridge **250** is connected to the barrel **230** by inserting the forward end of the front seal through the open end of the barrel **230** and screwing the cartridge clockwise into the aperture **296**. The frontal cavity **290** in the front seal **280** is preferably coaxial with the needle **212**, such that attachment of the cartridge **250** to the barrel **230** causes the proximal needle tip **214** to enter the cavity **290** and pierce the membrane **294**, thereby connecting the second chamber of the cartridge in fluid communication with

the needle **212**, as shown in Fig. 17.

Referring to Fig. 17, the cartridge **250** is connected to the barrel **230**, the medication can be injected into the patient by advancing the
5 cartridge forwardly into the barrel. The proximal end of the front seal **280** is configured to form a sliding fit with the interior of the cartridge **250** so that the cartridge slides over the front seal during advancement of the cartridge. As the cartridge **250** is advanced, the rearward end of the front seal **280** bears
10 against the needle retainer **220**, thereby keeping the front seal stationary during advancement of the cartridge. At the same time, the mid seal **270** at the rear of the second chamber **256** is displaced toward the front seal **280**. This causes a reduction of volume in the second chamber **256**, whereby the medication is displaced into the needle to facilitate the injection. At the
15 completion of the injection, the mid seal **270** bears against the rearward end of the front seal **280**, as shown in Fig. 22.

As in the previous embodiments, the needle **212** is retracted by actuating the needle retainer **220**. In particular, the needle **212** is retracted by
20 disengaging the retaining arms **222** from the retaining apertures **238** in the barrel wall to allow the spring **226** to propel the needle **212** rearwardly. To actuate the needle retainer **220**, pressure is applied to the cartridge **250** to advance the cartridge over the needle retainer body **221**, as shown in Fig. 22. During advancement, the distal end of the cartridge **250** engages a cylindrical
25 sleeve **300** that is disposed around the distal end of the needle retainer body **221**. The inside and outside diameters of the release sleeve **300** are preferably equal to the inside and outside diameters of the cartridge **250** so that the distal end of the cartridge mates with the proximal end of the sleeve. Prior to engagement with the cartridge **250**, axial movement of the release
30 sleeve **300** along the needle retainer is limited by an internal flange **302** that slides within an annular fluid passage **223** on the needle retainer body **221**. After the cartridge **250** engages the sleeve **300** continued advancement of

the cartridge drives the sleeve axially forwardly into engagement with the retaining arms **222**. The release sleeve **300** deflects the retaining arms radially inwardly and out of engagement with the retaining apertures **238**, allowing the spring **226** to propel the needle **212** rearwardly, as shown in Fig. 23.

As described above, the third embodiment includes a threaded engagement between the front seal **280** and the needle retainer **220** rather than a barbed connection as described in the first two embodiments. Using a threaded connection can increase the overall length of the needle retainer **220**, which in turn increases the distance between the distal end of the cartridge **250** and the retaining arms **222**. One manner for accommodating this increased length is to increase the length of the barrel **230**. However, by incorporating the release sleeve **300**, the length of the barrel **230** need not be substantially increased. The release sleeve **300** compensates for the increased distance by acting as an extension of the cartridge **250**. This eliminates the need to increase the overall length of the device **210**. Preferably, the length of the release sleeve **300** is slightly longer than the length of the threaded engagement between the front seal **280** and the needle retainer **220**.

Referring now to Figs. 24-29 in general, and to Figs. 24-25 specifically, a fourth embodiment of a pre-filled safety diluent injector is shown. The injector device **310** includes a double-ended needle **312**, a generally cylindrical barrel **330** that houses the needle and a generally cylindrical cartridge assembly **350** mounted within the proximal end of the barrel. Like the previous embodiments, the barrel further includes a compression spring **326** and a needle retainer **320** releasably retaining the needle **312** against the bias of the spring. The device **310** also includes a U-shaped locking clip **400** in the barrel wall to prevent accidental discharge of medication from the device **310**.

The cartridge assembly **350** has a two-part design that offers the advantage of using cost-efficient plastic in the assembly. The cartridge assembly **350** includes a front cylinder **351** having an open proximal end and a rear cylinder **353** having an open distal end telescopically mounted to the proximal end of the front cylinder. The front cylinder **351** contains an internal wall **360** that divides the cartridge assembly **350** into a first chamber **352** and a second chamber **356**. The first chamber **352** contains a predetermined amount of a first component **354** of medication, and the second chamber **356** contains a predetermined amount of a second component **358** of medication. The proximal end of the front cylinder **351** is closed by a pierceable elastomeric front seal **380**.

In many applications, the second component **358** will be a dry powdered component. Dry components do not require a glass container and can be stored in plastic containers without jeopardizing long term stability of the component. Since it is more cost-efficient to mold complex parts out of plastic than glass, it is preferable to minimize the complexity of the glass portion of the cartridge assembly **350**. To this end, the front and rear cylinders **351**, **353** are configured so that the first component **354** is stored entirely within the rear cylinder and the second component **356** is stored entirely within the front cylinder. In this arrangement, the front cylinder **351** comprises a more complicated structure to allow the rear cylinder to be a simple cup-shaped container. Therefore, the more complex forward cylinder can be molded out of cost-efficient plastic for those devices that store a dry second component **358** in the second chamber **356**. Preferably, glass is only used, if at all, to mold the rear cylinder **353**.

As stated earlier, the rear cylinder **353** is telescopically mounted on the proximal end of the front cylinder **351**. The outside diameter of the rear portion of the rear seal is generally equal to the inside diameter of the rear cylinder **353** so as to frictionally engage the interior of the rear cylinder

and provide a fluid tight seal. The rear cylinder **353** is adapted to slide axially over the rear seal **340** in response to pressure applied to the proximal end of the rear cylinder.

5 The barrel **330** has an inside diameter large enough to accommodate the outside diameter of the rear cylinder **353**. As a result, the outside wall of the front cylinder **351** is separated from the interior wall of barrel **330** by a clearance space, as shown in Fig. 25. The front cylinder **351** is maintained in a concentric relationship with the much larger barrel **330** by a
10 pair of opposing longitudinal ribs **355** on the outside wall of the front cylinder. The longitudinal ribs are illustrated in Fig. 24.

 An elastomeric rear seal **340** is disposed between the front cylinder **351** and rear cylinder **353**. The rear seal **340** includes a reduced
15 diameter end **342** partially disposed in the open proximal end of the front cylinder **351**. The rear seal **340** also includes a flanged end **344** disposed within the rear cylinder **353**. The reduced diameter end **342** and flanged end **344** frictionally and sealingly engage the interior of the front cylinder **352** and rear cylinder **354**, respectively. This engagement provides a fluid tight seal
20 with the interior of both cylinders, while allowing the rear seal **340** to be displaced relative to either cylinder. Forward advancement of the rear seal **340** relative to the front cylinder **351** is limited by the proximal end of the front cylinder, which is configured to matingly engage the flanged portion of the rear seal.

25 As stated earlier, the front cylinder **351** contains an internal wall **360**. The internal wall **360** is adjacent the rearward open end of the cartridge, forming a socket for receiving the rear seal **340**. The internal wall **360** contains an orifice **362** mounted in the center of the wall **360**. A hollow
30 piercing member **364** is mounted in the orifice and extends rearwardly toward the rear seal **340**. In addition, it may be desirable to provide a vent opening in

the internal wall **360** to vent the air between the rear seal **340** and the internal wall when the rear cylinder is advanced to pierce the rear seal.

5 The distal end of the rear seal **340** is closed by a membrane **348** that is configured to be pierced by piercing member **364**. The rear seal **340** includes a hollowed mid section **346** that is connected in fluid communication with the first chamber **352** through the proximal end of the rear seal. Once the membrane **348** is pierced, a fluid passage is created through the piercing member **364** and rear seal **340**, such that the first and
10 second chambers, **352**, **356** are connected in fluid communication. The rear seal **340** may be molded in a high elongation self-sealing biocompatible elastomer, such as polyisoprene.

15 The operation of the device **310** will now be described. A slight squeezing pressure is applied to the proximal end of the rear cylinder **353** to axially advance the rear cylinder over the front cylinder **351**. This causes the first component **354** to become compressed between the rear seal **340** and the closed proximal end of the rear cylinder **353**. Continued pressure on the rear cylinder **353** creates back pressure on the rear seal **340** which axially
20 displaces the rear seal forwardly into the piercing member **364**. At this time, the membrane **348** is pierced to create a fluid passage between the first and second chambers **352**, **356**.

25 The rear cylinder **353** is advanced forwardly relative to the front cylinder **351** to expel the first component **354** from the first chamber **352** into the second chamber **356**. Once the first component **354** is completely expelled from the first chamber **352**, additional pressure on the rear cylinder **353** advances the rear cylinder forwardly relative to the front cylinder **351** until the closed proximal end of the rear cylinder abuts the proximal end of the rear
30 seal **340**, as shown in Fig. 26. At this point, the device **310** is shaken to mix the components within the second chamber **356**. During the mixing process,

displacement of the cartridge assembly **350** is prevented by the locking clip **400**, thereby minimizing the potential for accidental discharge of the medication.

5 After the components are mixed, the locking clip **400** is removed. The cartridge assembly is then displaced forwardly so that the rearward end of the needle **312** pierces the forward seal **380**. The air is then
10 vented from the forward chamber. Further pressure is applied to the cartridge assembly **350** to discharge the medication from the second chamber **356** and
15 through the needle **312**. At the completion of the injection stroke, the proximal end of the cartridge assembly **350** actuates the needle retainer **320**,
20 as shown in Fig. 27. Pressure on the cartridge assembly **350** is then released so that the needle **312** can be retracted, as shown in Figs. 28 and 29.

15 In some instances, it may be desirable to store the cartridge in its component parts. In other words, the rear cylinder **353** may be detached from the forward cylinder **351**. Prior to use, the rear cylinder **353** would be
20 attached to the forward cylinder **351** and the combined assembly would be utilized as described above. In such instances, the separate rear container
25 **353** may include a separate cap to cover its forward end. Similarly, the forward cylinder **351** may include a cap to cover its rearward end. The detachable rearward cylinder **353** may permit a variety of pre-measured medicinal components to be stored and readily combined in various combinations prior to use.

25 The terms and expressions which have been employed are used as terms of description and not of limitation. There is no intention in use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof. It is recognized, however, that
30 various modifications of the embodiments described herein are possible within the scope and spirit of the invention. For instance, the embodiments

described above include a needle retainer having a pair of radially
displaceable arms to automatically release the needle for retraction after use.
However, the devices may be modified by utilizing different needle retainers
that may or may not automatically retract the needle after use. Accordingly,
5 the invention incorporates variations that fall within the scope of the following
claims.

CLAIMS

1. A medical device, comprising:
 - a barrel having an open proximal end and a distal end;
 - a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;
 - a cartridge in fluid communication with the needle, comprising:
 - a first chamber containing a first substance;
 - a second chamber containing a second substance;
 - a fluid flow controller between the first chamber and the second chamber; and
 - a plunger slidably disposed within the cartridge;
 - a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip; and
 - a needle retainer releasably retaining the needle in the extended position;

wherein axially advancing the plunger within the first chamber advances the first substance through the fluid flow controller and into the second chamber where said first substance combines with the second substance to form a medicinal mixture, and continued advancement of the plunger and cartridge relative to the barrel after the mixture is expelled from the cartridge actuates the needle retainer to release the needle, whereupon the biasing element displaces the needle relative to the barrel to shield the first sharpened tip.
2. The medical device in claim 1 wherein the medical device further comprises a needle carrier fixed to the needle.
3. The medical device in claim 1 wherein the needle has a second sharpened tip at its rearward end.

4. The medical device in claim 1 wherein the needle is retracted upon release of pressure on the plunger.
5. The medical device in claim 1 wherein the medical device further comprises one or more stops that impede continued rearward displacement of the first sharpened needle tip beyond the proximal end of the barrel as the needle is moved to the shielded position.
6. The medical device in claim 1 wherein the plunger is comprised of a plastic molded plunger rod connected to an elastomeric seal.
7. The medical device in claim 1 wherein the plunger is displaceable relative to the cartridge while the first substance is expelled from the first chamber, and the plunger is stationary relative to the cartridge when the mixture is expelled from the second chamber.
8. The medical device in claim 1 wherein the second substance is a powdered material.
9. The medical device in claim 1 wherein the second substance is a liquid material.
10. The medical device in claim 1 wherein the volume of the second chamber is greater than the combined volume of the first substance and the second substance.
11. The medical device in claim 1 wherein the fluid flow controller comprises:
 - a wall between the first and second chambers having an opening;
 - a hollow piercing element disposed through the opening having a sharpened end extending into the first chamber; and
 - a fluid flow pathway through the piercing element;wherein axially displacing the cartridge toward the barrel displaces the plunger until the plunger is ruptured by the piercing element,

creating a passage through the plunger which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the plunger into the second chamber.

12. The medical device in claim 1 wherein the fluid flow controller comprises:
 - a barrier between the first and second chambers having an opening;
 - a hollow piercing element disposed through the opening having a sharpened end extending into the first chamber;
 - a fluid flow pathway through the piercing element; and
 - a pierceable mid seal axially displaceable within the first chamber that provides fluid communication between the first and second chambers upon being pierced by the piercing element;wherein axially displacing the plunger toward the barrel displaces the pierceable mid seal until the mid seal is ruptured by the piercing element, creating a passage through the mid seal which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the mid seal into the second chamber.
13. The medical device in claim 1 wherein the fluid flow controller comprises:
 - a mid seal between the first and second chambers that is axially displaceable within the cartridge; and
 - an elongated fluid passage in the side wall of the cartridge;wherein axially displacing the plunger toward the barrel displaces the mid seal into alignment with the fluid passage, creating a passage between said mid seal and the inside wall of the fluid passage that allows the first substance to flow around the mid seal into the second chamber.
14. The medical device in claim 1 wherein the cartridge is substantially permanently attached to the barrel.

15. The medical device in claim 1 wherein the cartridge comprises a beaded circumferential rim on the distal end of the cartridge, and the barrel contains a lip projecting radially inwardly from the inner bore of the barrel at the barrel's proximal end, said lip adapted to engage the beaded rim of the cartridge to impede removal of the cartridge from the rear of the barrel after needle retraction.
16. The medical device in claim 2 wherein the biasing element comprises a compression spring disposed between the distal end of the barrel and the needle carrier.
17. The medical device in claim 2 wherein the needle retainer comprises a pair of forward tines extending radially outwardly from the needle carrier and configured to releasably engage a pair of windows in the barrel wall.
18. The medical device in claim 2 wherein a cylindrical sleeve having generally the same outside diameter as the cartridge is disposed around the circumference of the needle carrier in general axial alignment with the cartridge, such that axial advancement of the cartridge at the end of the injection stroke displaces the sleeve toward the distal end of the barrel to actuate the needle retainer.
19. The medical device in claim 3 wherein the cartridge further comprises a front seal at the distal end of the cartridge that is configured to be pierced by the second sharpened tip to connect the needle and second chamber in fluid communication.
20. The medical device in claim 19 wherein the minimum axial force on the plunger that is required to pierce the front seal is less than or equal to the minimum axial force required to axially displace the plunger in the rear chamber.
21. The medical device in claim 19 wherein the distal end of the front seal

includes an external thread and the proximal end of the needle carrier includes a cavity adapted to receive the threaded end of the front seal.

22. A medical device, comprising:
- a barrel having an open proximal end, a distal end and an opening through the barrel wall oriented perpendicularly to the longitudinal axis of the barrel;
 - a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;
 - a cartridge in fluid communication with the needle, comprising:
 - a first chamber containing a first substance;
 - a second chamber containing a second substance;
 - a fluid flow controller connecting the first chamber and the second chamber; and
 - a plunger slidably disposed within the cartridge;
 - a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip;
 - a needle retainer releasably retaining the needle in the extended position; and
 - a locking clip detachably connected to the barrel;
- wherein axially advancing the plunger within the first chamber advances the first substance through the fluid flow controller and into the second chamber where said first substance combines with the second substance to form a medicinal mixture, and removal of the locking clip from the barrel permits further advancement of the plunger and cartridge relative to the barrel to expel the mixture from the second chamber, whereafter axially advancing the cartridge disengages the needle retainer to allow the biasing element to displace the needle relative to the barrel to shield the first sharpened tip.

23. The medical device in claim **22** wherein the medical device further comprises a needle carrier fixed to the needle.
24. The medical device in claim **22** wherein the needle has a second sharpened tip at its rearward end.
25. The medical device in claim **22** wherein the needle is retracted upon release of pressure on the plunger.
26. The medical device in claim **22** wherein the cartridge comprises a beaded circumferential rim on the distal end of the cartridge, and the barrel contains a lip projecting radially inwardly from the inner bore of the barrel at the barrel's proximal end, said lip adapted to engage the beaded rim of the cartridge to impede removal of the cartridge from the rear of the barrel after needle retraction.
27. The medical device in claim **22** wherein the medical device further comprises one or more stops that impede continued rearward displacement of the first sharpened tip beyond the open proximal end of the barrel as the needle is moved to the shielded position.
28. The medical device in claim **22** wherein the plunger is comprised of a plastic molded plunger rod connected to an elastomeric seal.
29. The medical device in claim **22** wherein the plunger is displaceable relative to the cartridge while the first substance is expelled from the first chamber, and the plunger is stationary relative to the cartridge when the mixture is expelled from the second chamber.
30. The medical device in claim **22** wherein the locking clip comprises a flat U- shaped disk having a plurality of teeth along the inner edge, said clip being configured to slide through the slits in the barrel in a direction perpendicular to the longitudinal axis of the barrel and at a location between the cartridge and the needle retainer, thereby impeding

contact between the cartridge and the needle retainer.

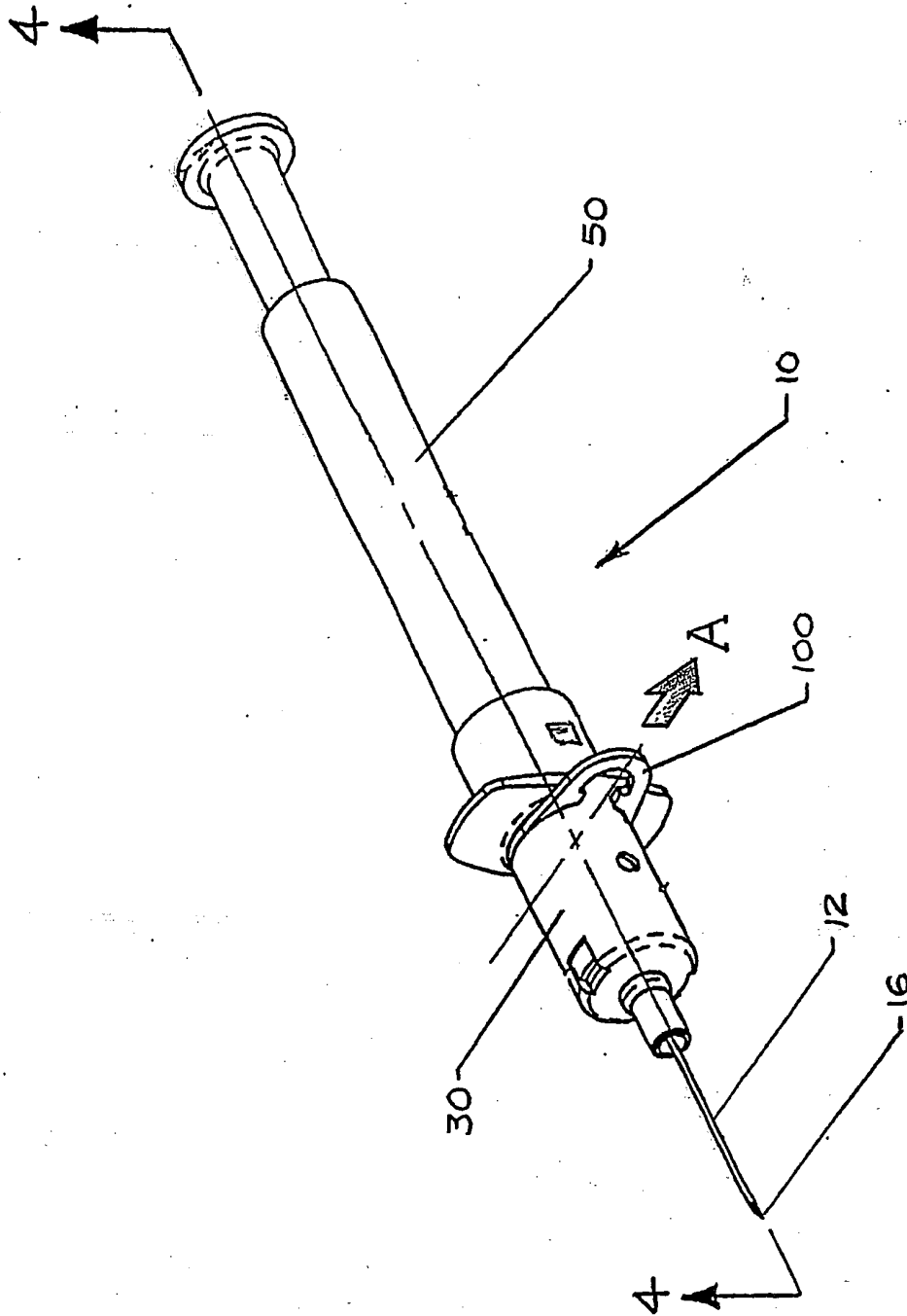
31. The medical device in claim **22** wherein the second substance is a powdered material.
32. The medical device in claim **22** wherein the second substance is a liquid material.
33. The medical device in claim **22** wherein the volume of the second chamber is greater than the combined volume of the first substance and the second substance.
34. The medical device in claim **22** wherein the fluid flow controller comprises:
 - a barrier between the first and second chambers having an opening;
 - a hollow piercing element disposed through the opening having a sharpened end extending within the first chamber;
 - a fluid flow pathway through the piercing element; and
 - a pierceable mid seal axially displaceable within the first chamber that provides fluid communication between the first and second chambers upon being pierced by the piercing element;wherein initial axial displacement of the plunger toward the barrel displaces the pierceable mid seal into contact with the piercing element, piercing the mid seal and creating a passage through the mid seal which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the mid seal into the second chamber.
35. The medical device in claim **22** wherein the fluid flow controller comprises:
 - a mid seal between the first and second chambers that is axially displaceable within the cartridge; and
 - an elongated fluid passage in the side wall of the cartridge between the

mid seal and the distal end of the cartridge;
wherein axially displacing the plunger toward the barrel displaces the mid seal into alignment with the fluid passage, creating a passage between said mid seal and the inside wall of the fluid passage that allows the first substance to flow around the mid seal into the second chamber.

36. The medical device in claim **23** wherein the biasing element comprises a compression spring disposed between the distal end of the barrel and the needle carrier.
37. The medical device in claim **23** wherein the needle retainer comprises a pair of forward windows in the barrel wall and a pair of forward tines extending radially outwardly from the needle carrier and configured to releasably engage the forward windows.
38. The medical device in claim **24** wherein the cartridge further comprises a front seal at the distal end of the cartridge that is configured to be pierced by the second sharpened tip to connect the needle and second chamber in fluid communication.
39. The medical device in claim **38** wherein the minimum axial force on the plunger that is required to pierce the front seal is less than or equal to the minimum axial force required to axially displace the plunger in the rear chamber.
40. A medical device, comprising:
 - a barrel having an open proximal end and a distal end;
 - a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;
 - a cartridge in fluid communication with the needle, comprising:

a first chamber containing a first substance;
a second chamber containing a second substance;
a fluid flow controller between the first chamber and the second chamber; and
a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip; and
a needle retainer releasably retaining the needle in the extended position;
wherein the fluid flow controller is adapted to keep the first and second substances separate prior to use, and also adapted to allow mixing of the first and second substances prior to an injection, wherein after use the needle is disposed in the shielded position.

41. A method for injecting medicine, comprising the steps of:
providing an injection device having a first chamber containing a first medicinal component, a second chamber containing a second medicinal component, and a needle;
transferring the first medicinal component from the first chamber to the second chamber;
mixing the first and second components to form a medicinal mixture;
expelling the medicinal mixture from the chamber; and
retracting the needle after expelling the medicinal fluid to shield the needle against contact.

Figure 1

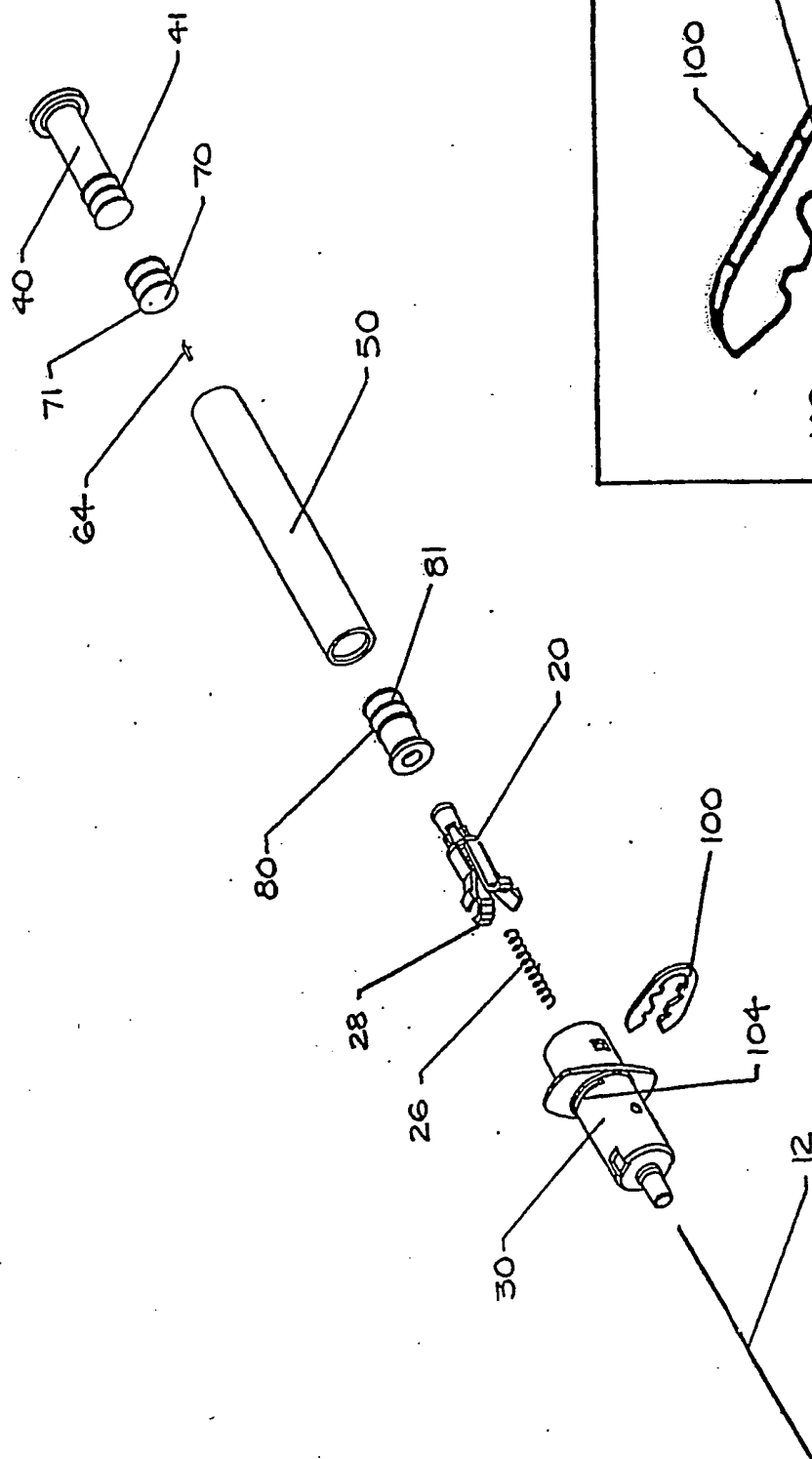


Figure 2

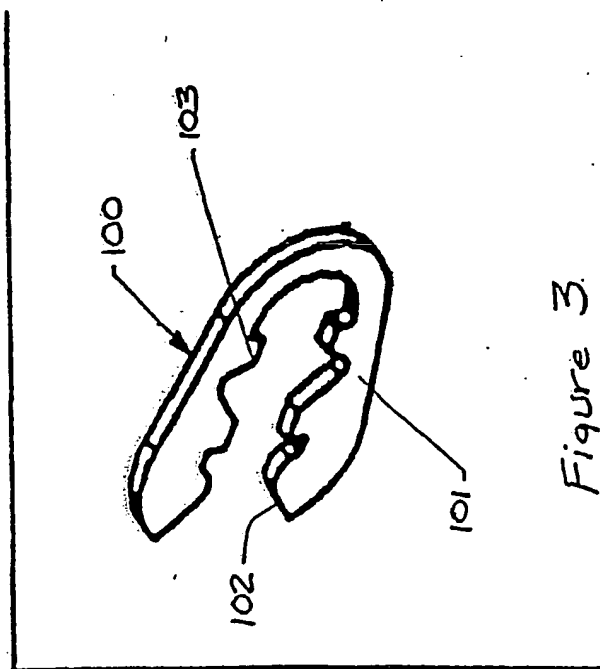
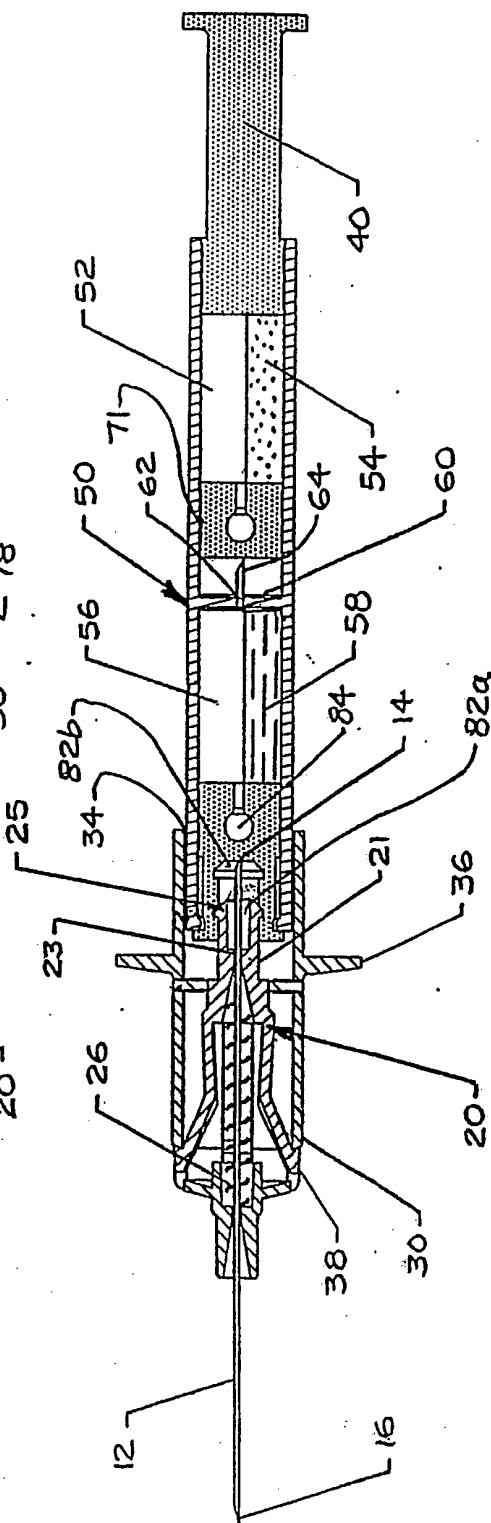
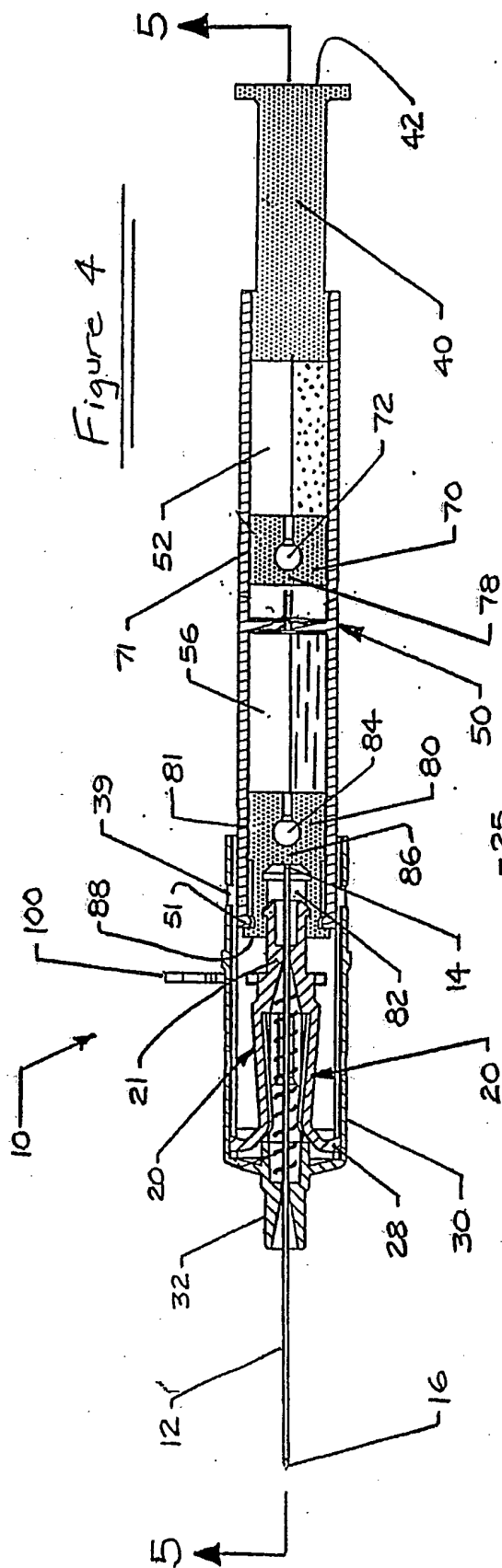


Figure 3



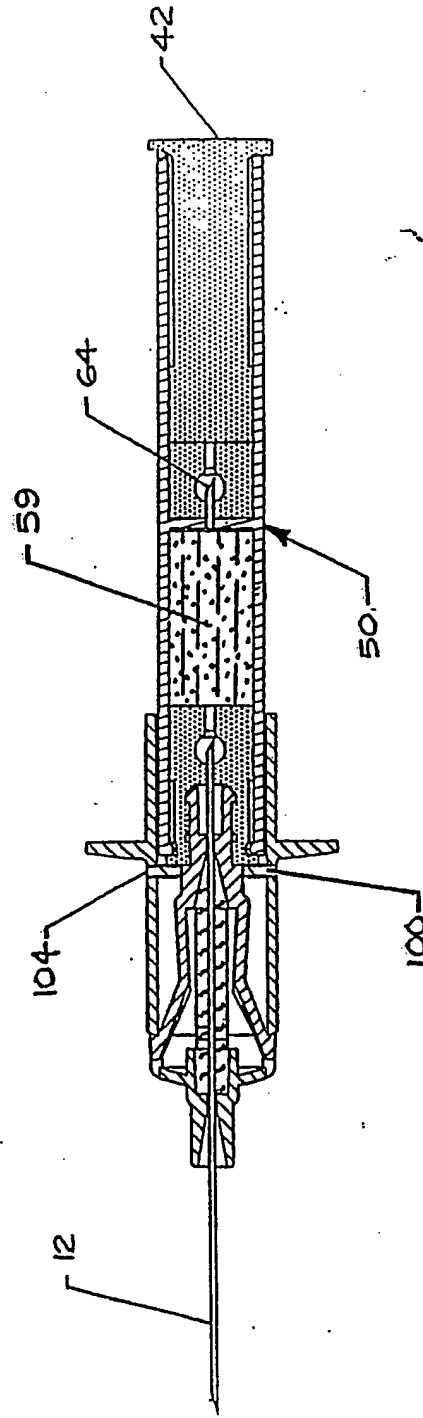
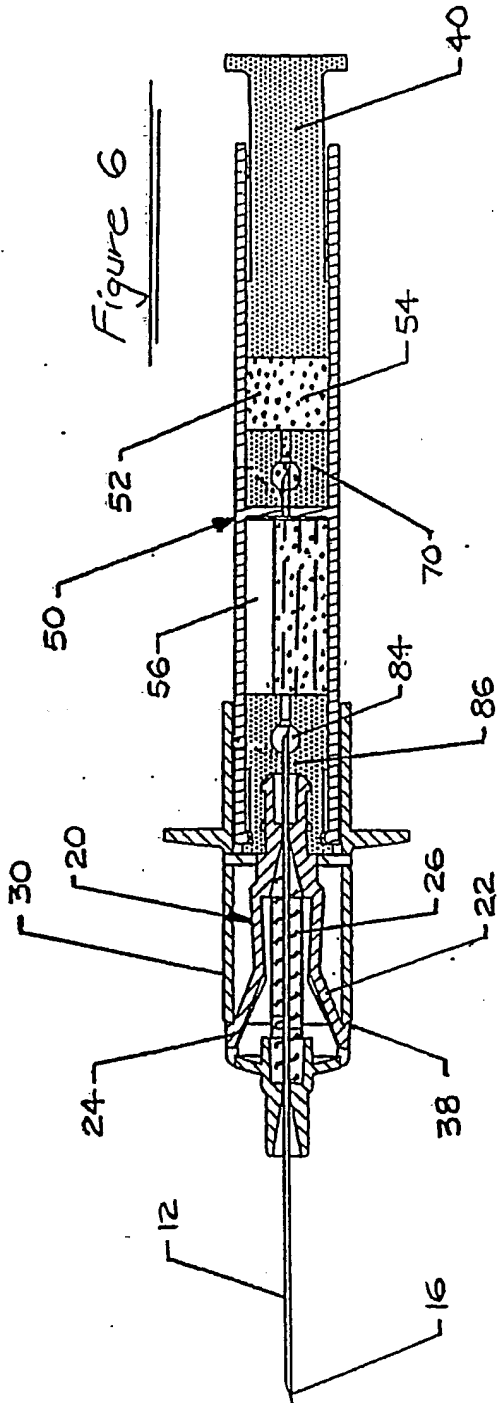


Figure 8

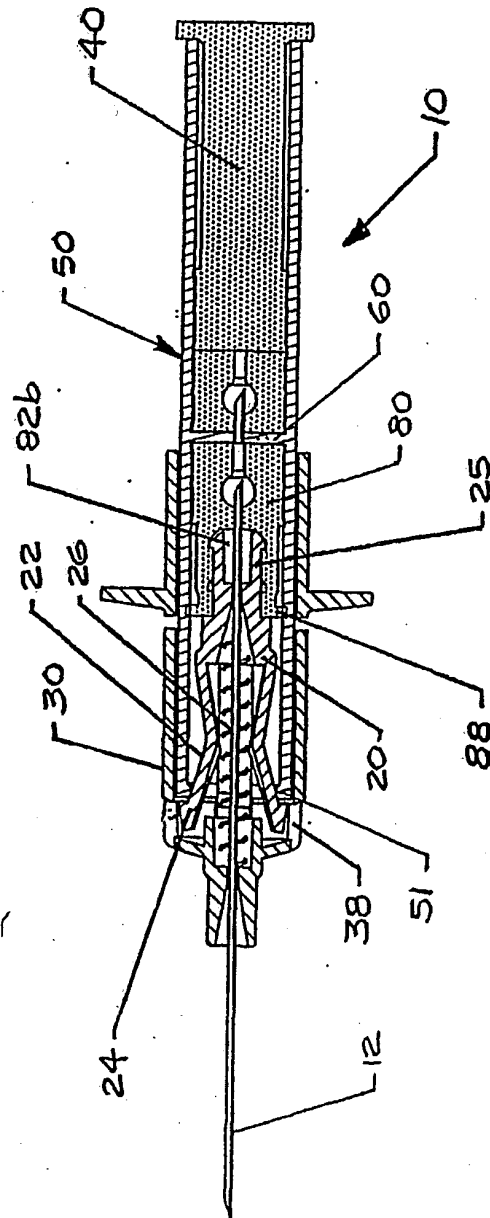
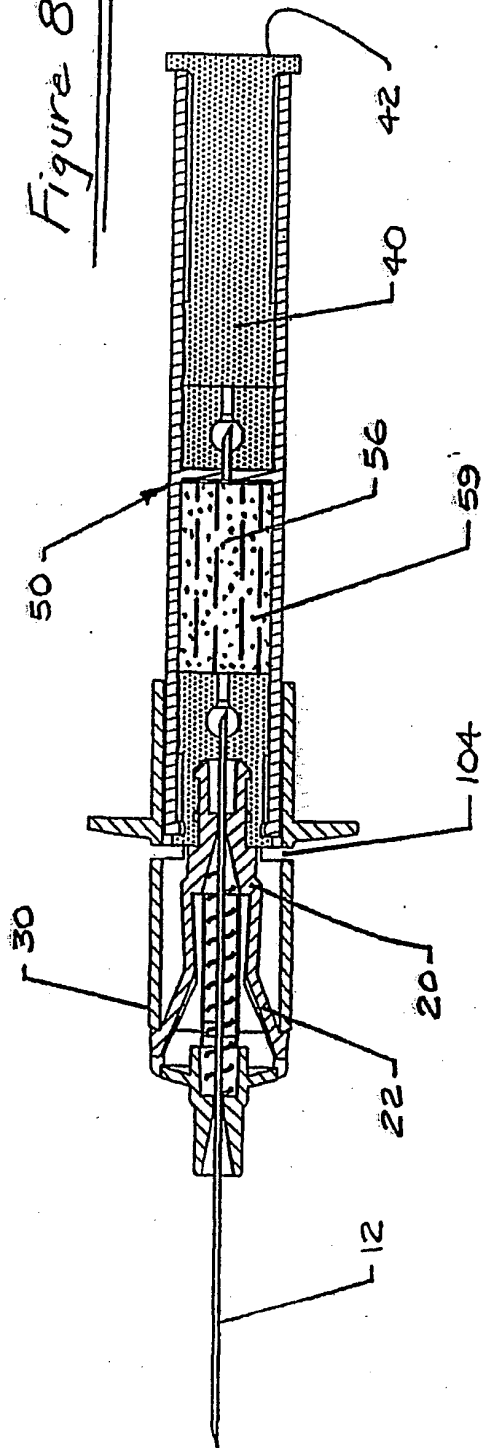


Figure 9

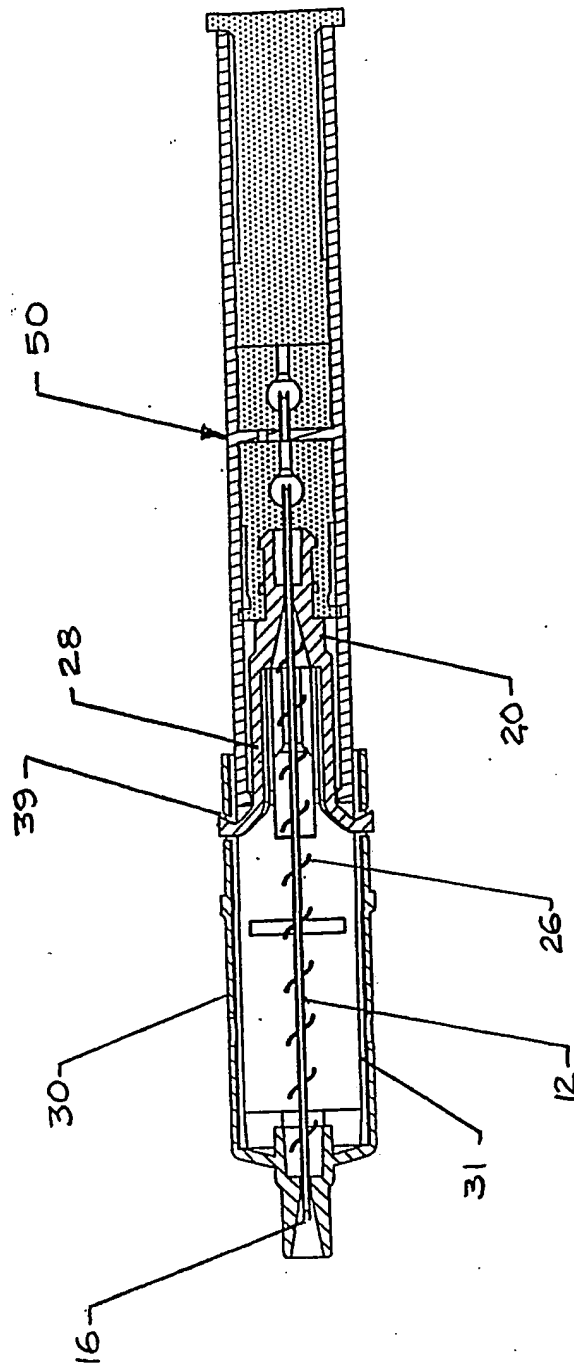


Figure 10

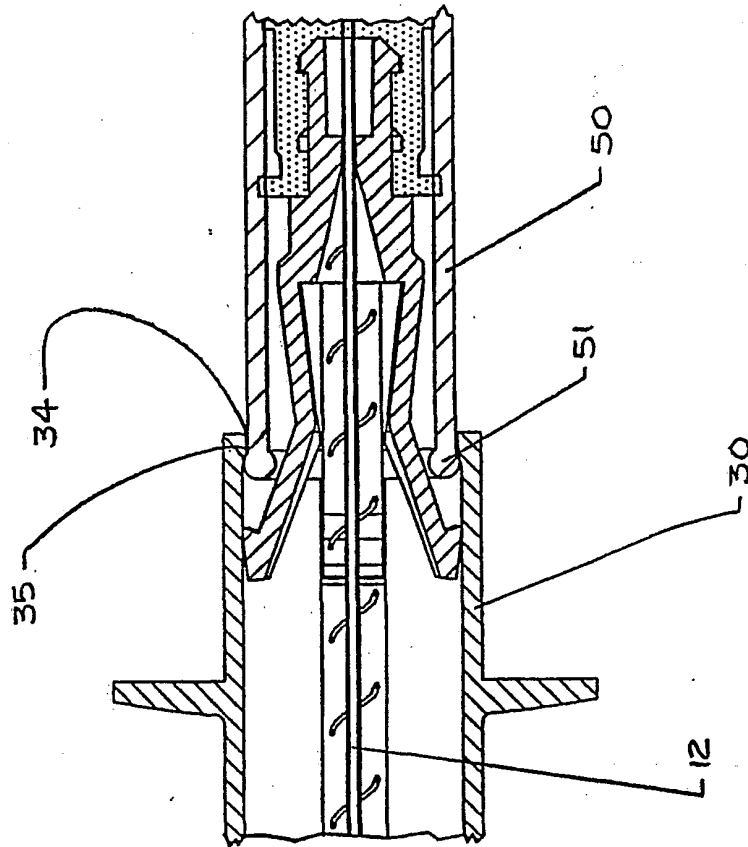
Figure 11

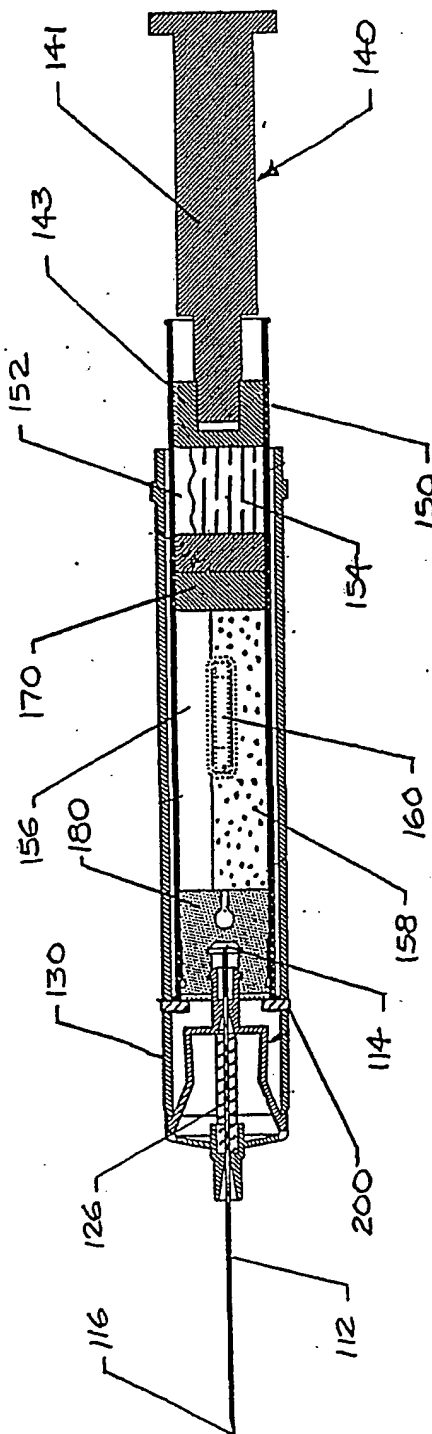
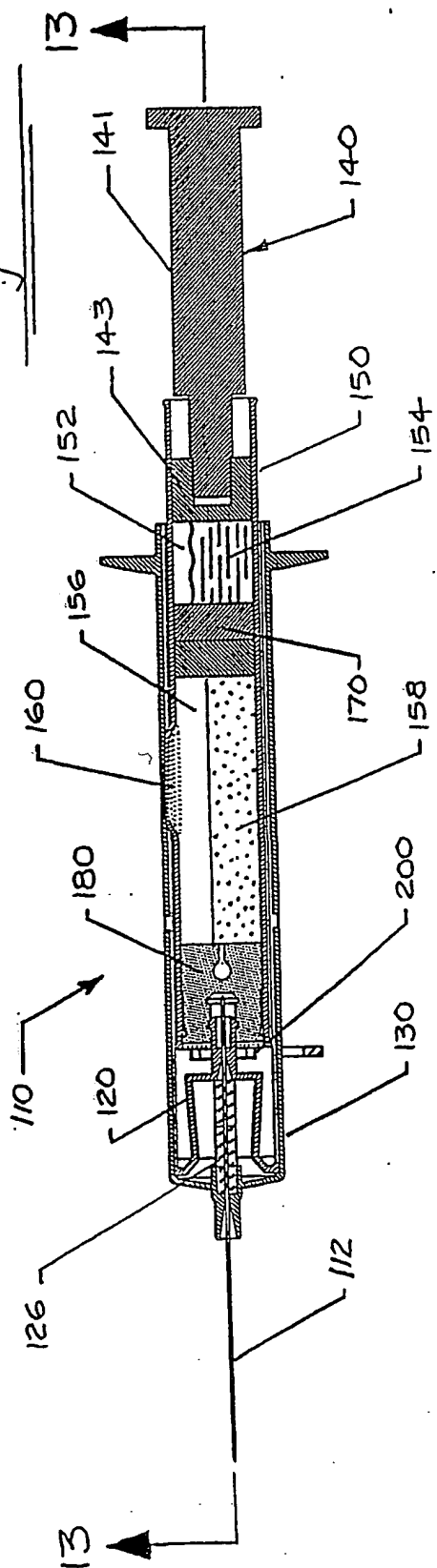
Figure 12Figure 13

Figure 14

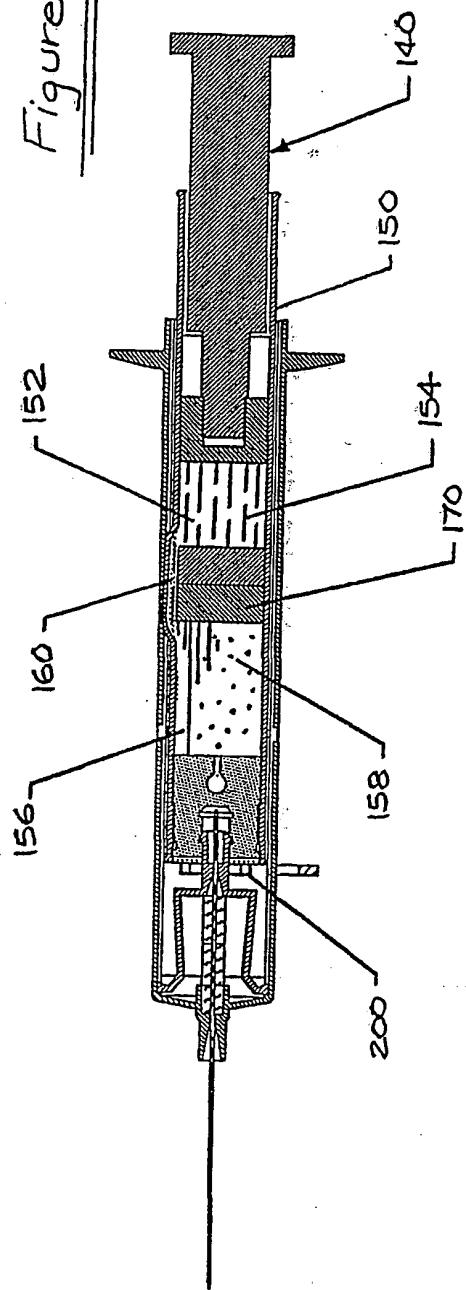
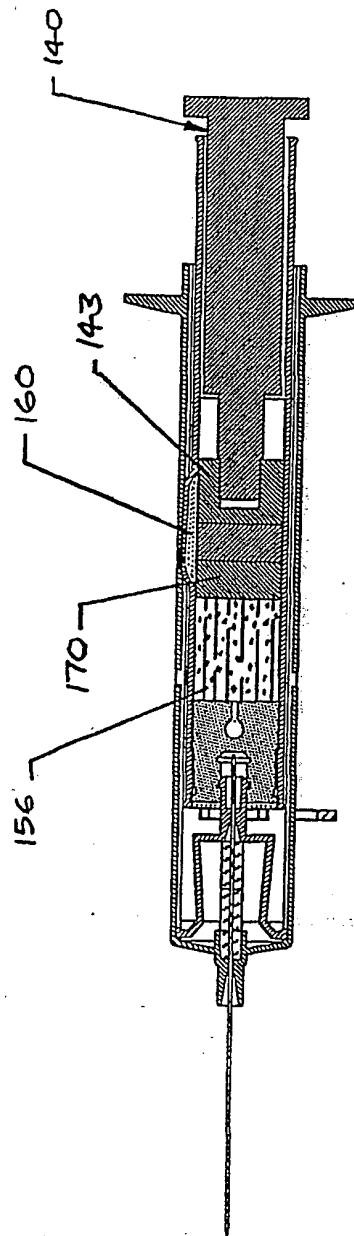


Figure 15



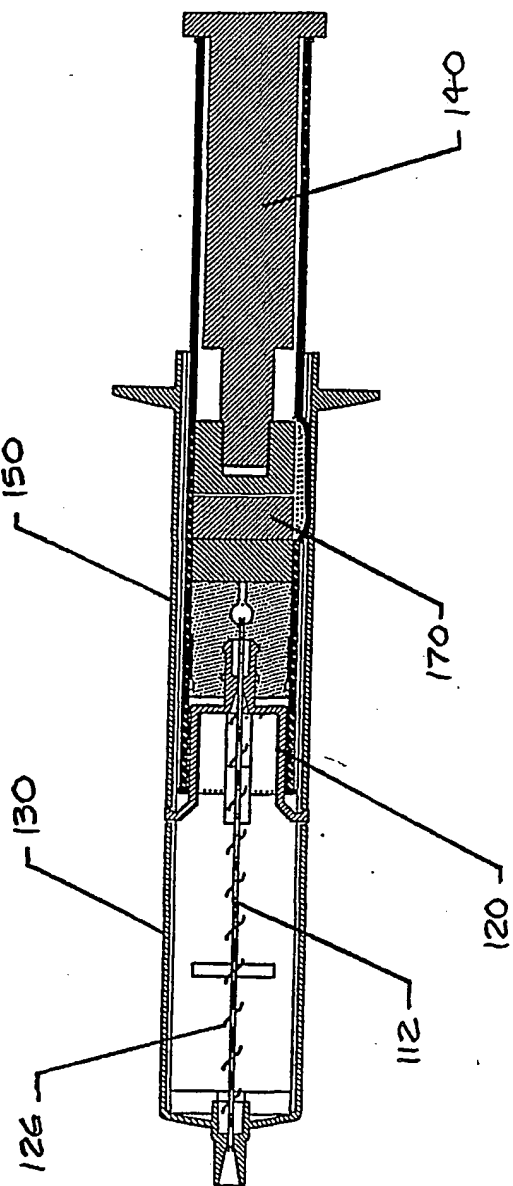


Figure 16

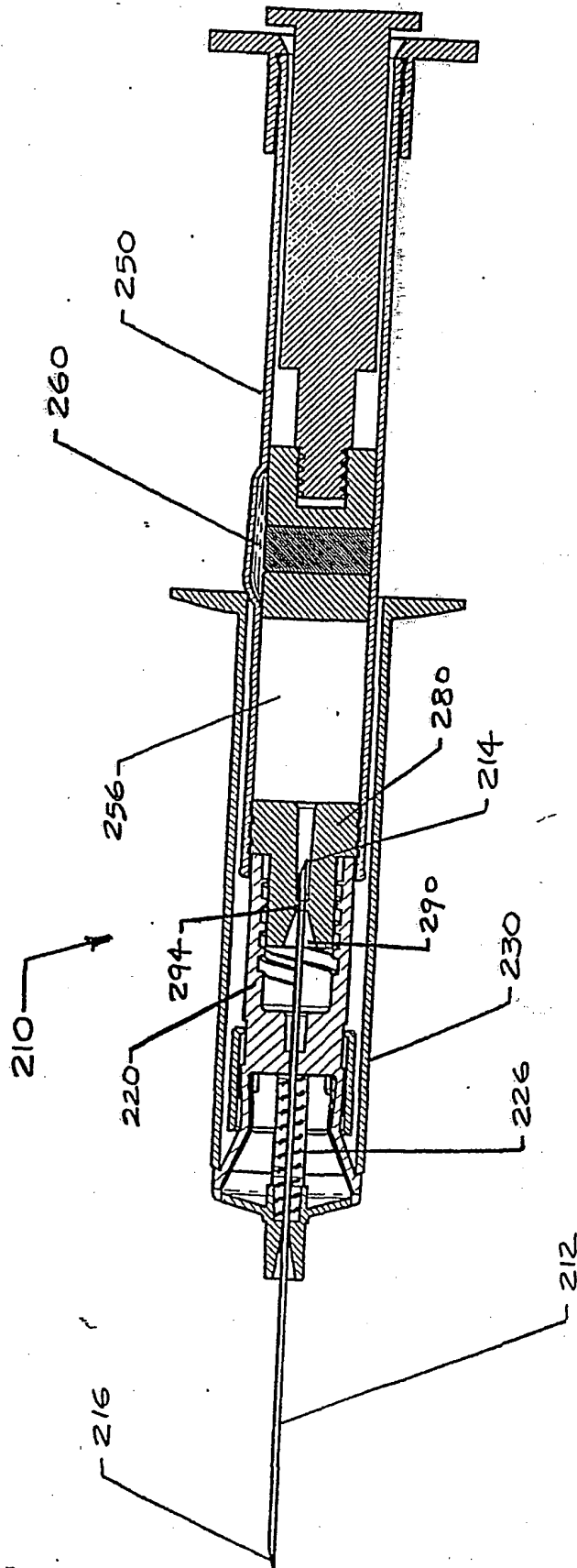


Figure 17

Figure 18

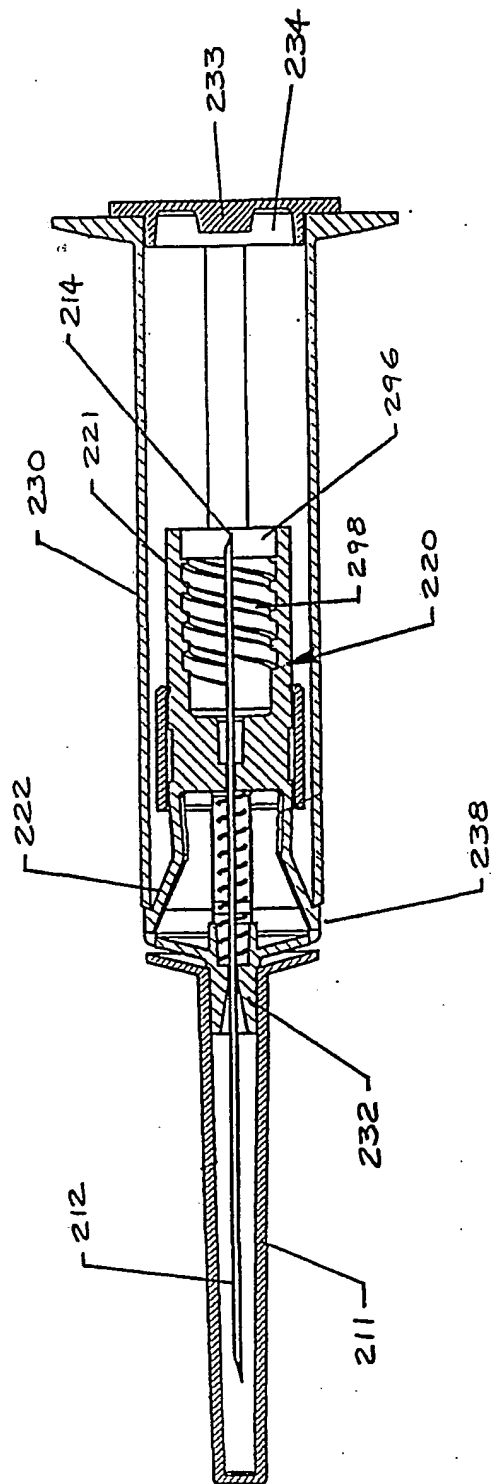
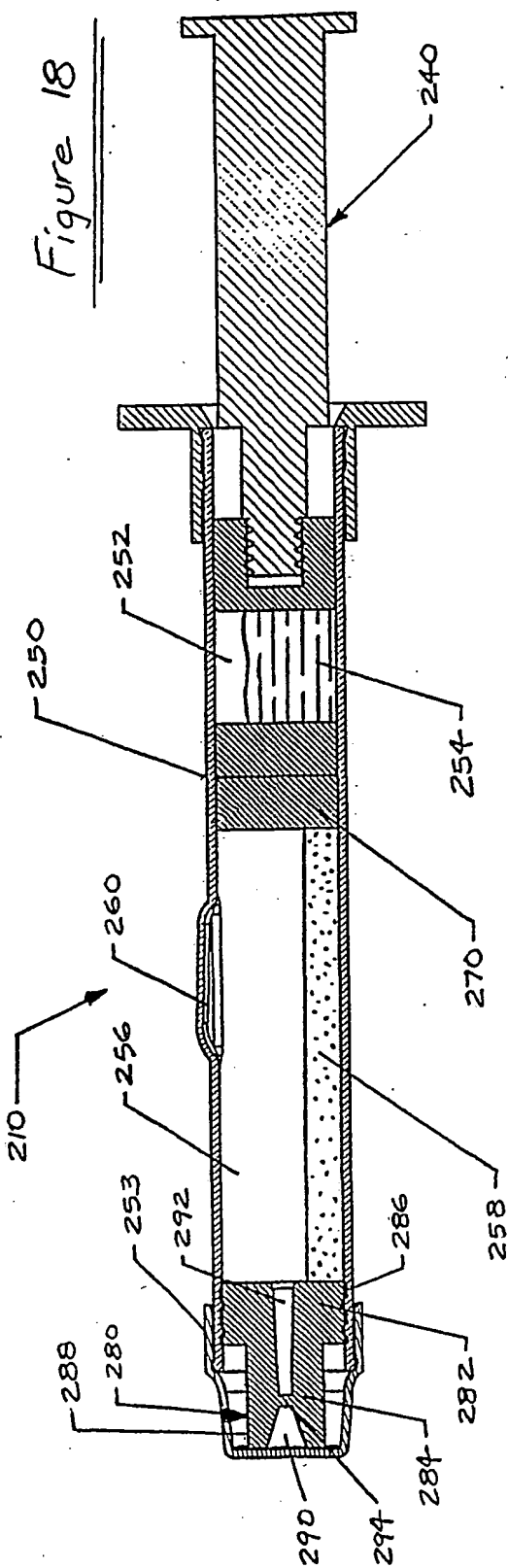


Figure 19

Figure 20

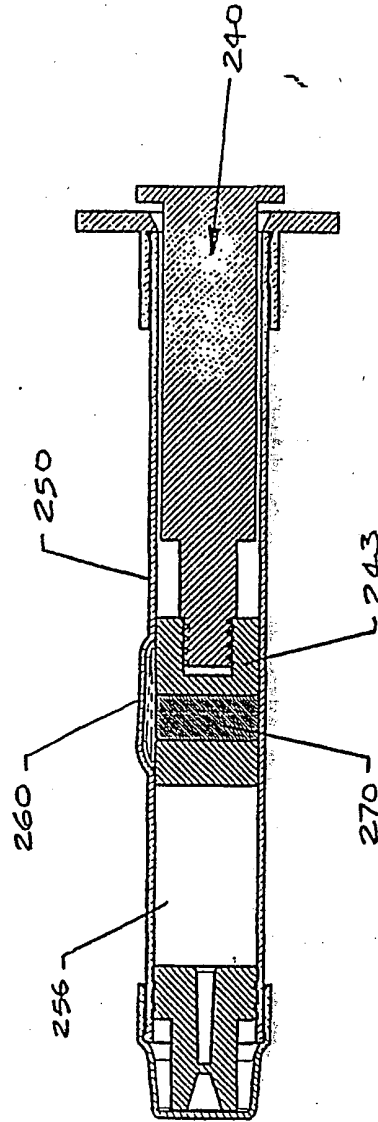
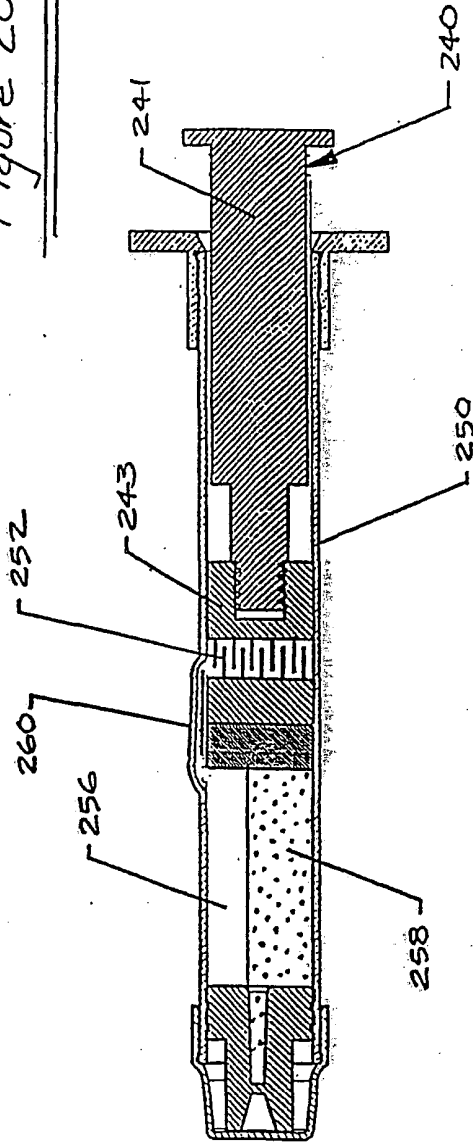


Figure 21

This cross-sectional view shows a medical device with a central catheter (212) passing through a series of internal components. From left to right, these include a valve assembly (220) with a diaphragm (222), a chamber (230) containing a piston (280), and a distal section (250) with a porous tip (270). The device is housed within a main body (300) with various internal seals and structures.

This cross-sectional view shows a medical device with a central shaft (212) and a proximal handle assembly (226). The handle assembly includes a trigger mechanism (222) with a trigger finger (223) and a trigger spring (224). A trigger button (225) is located on the handle. A proximal seal (221) is positioned at the proximal end of the shaft. A proximal connector (238) is located at the proximal end of the shaft. A proximal seal (221) is positioned at the proximal end of the shaft. A proximal connector (238) is located at the proximal end of the shaft. A proximal seal (221) is positioned at the proximal end of the shaft. A proximal connector (238) is located at the proximal end of the shaft.

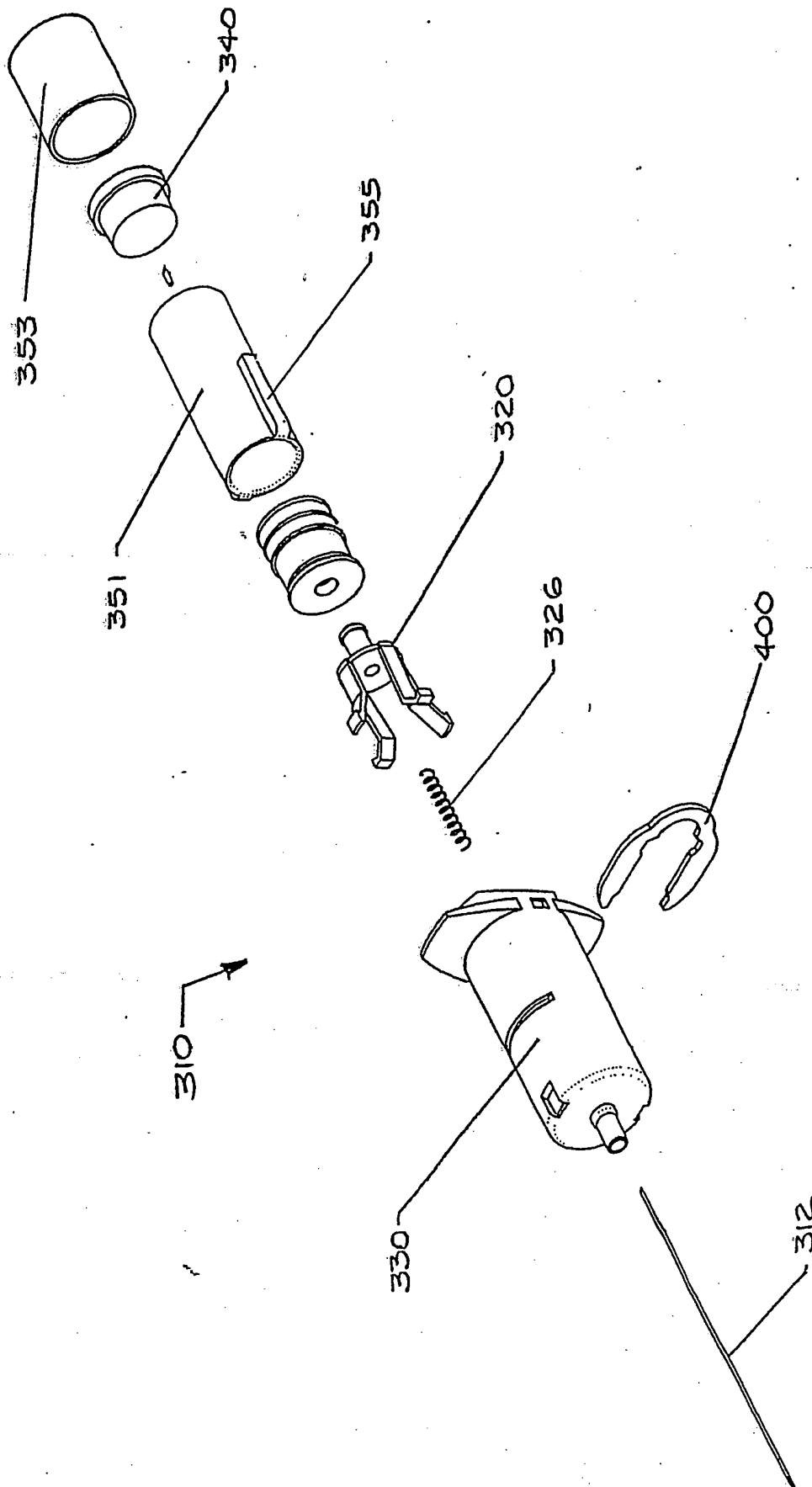
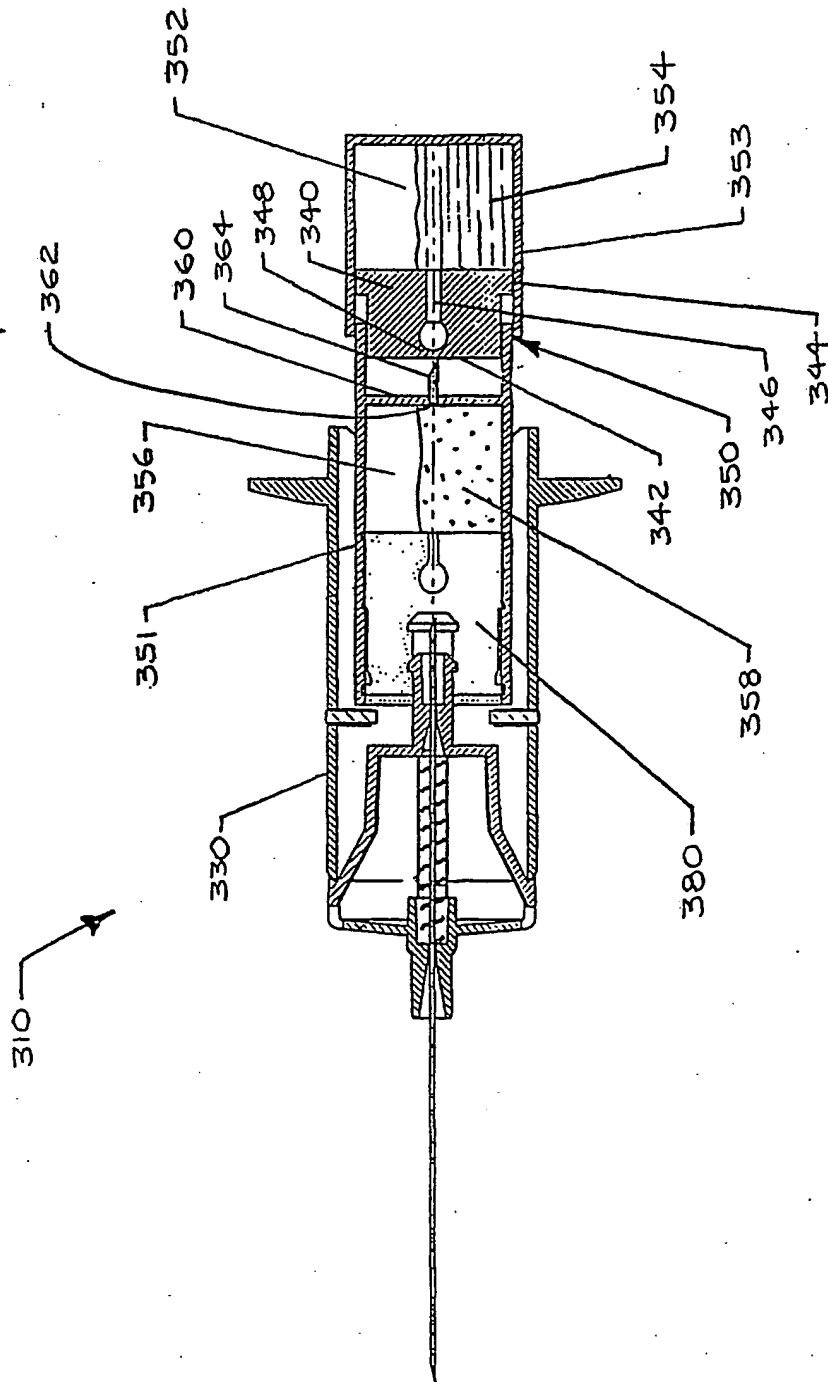


Figure 24

Figure 25

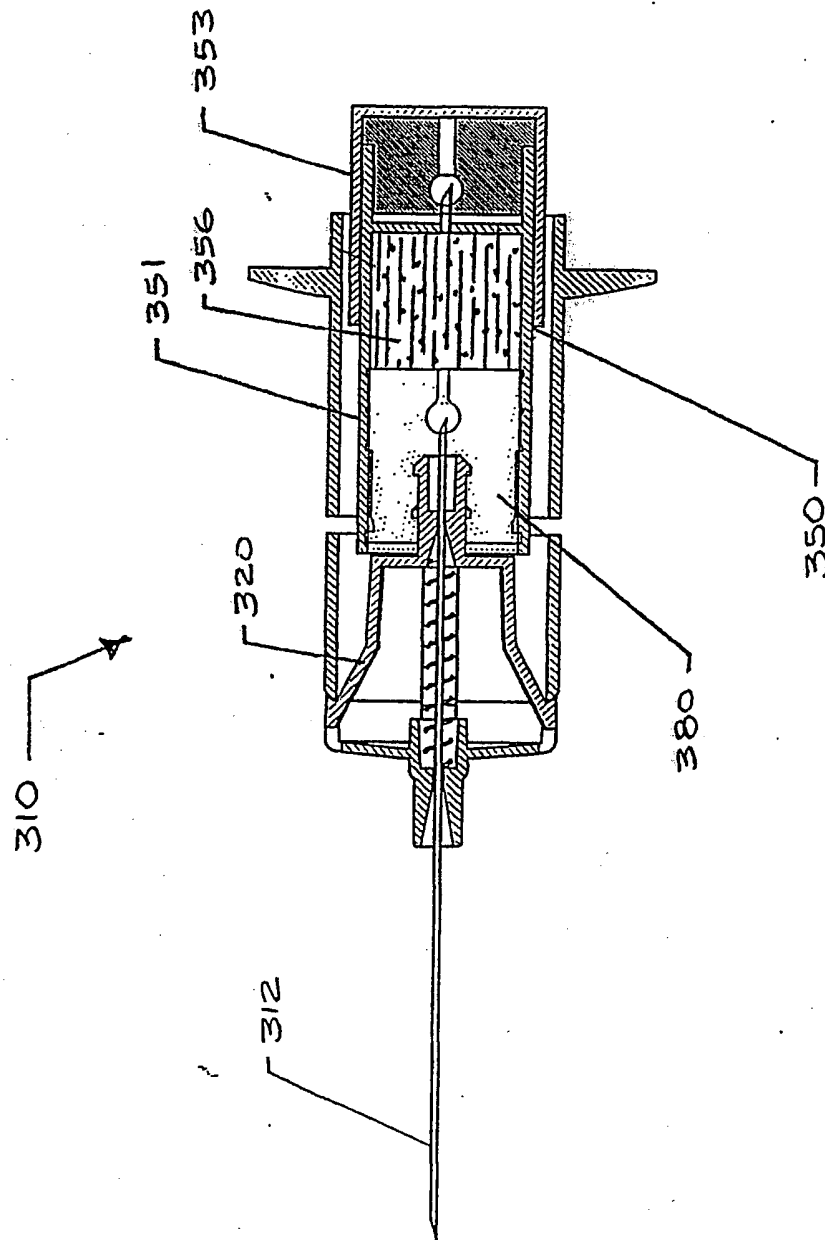
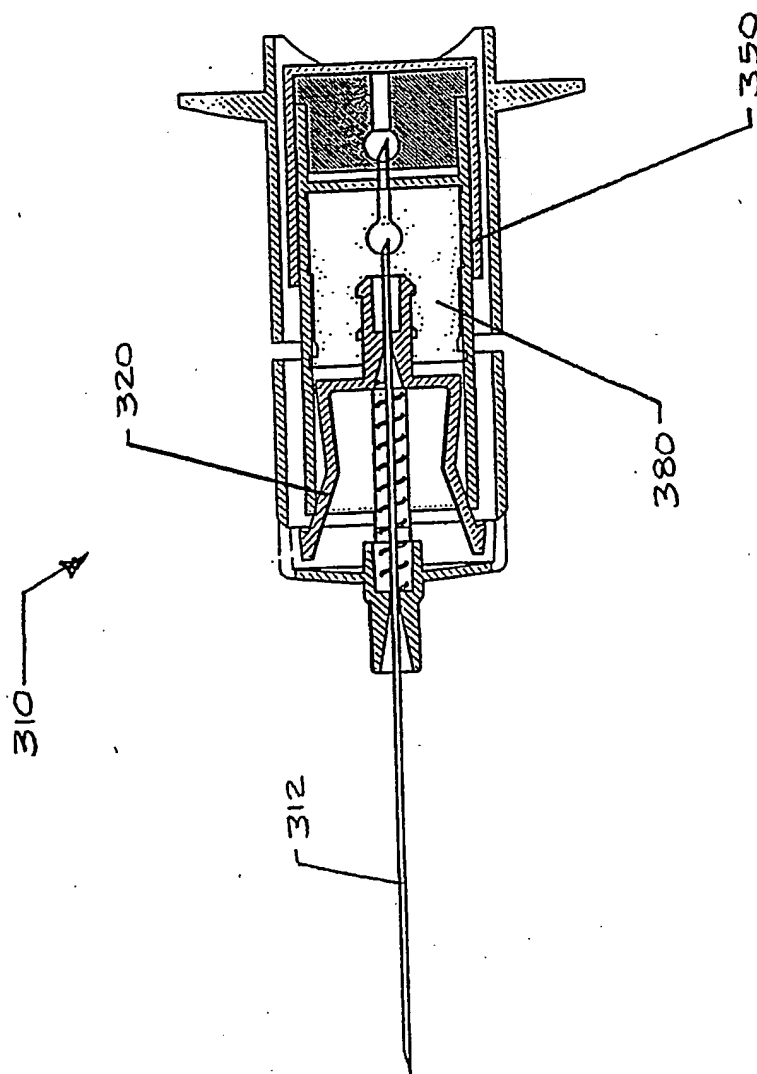


Figure 26

Figure 27

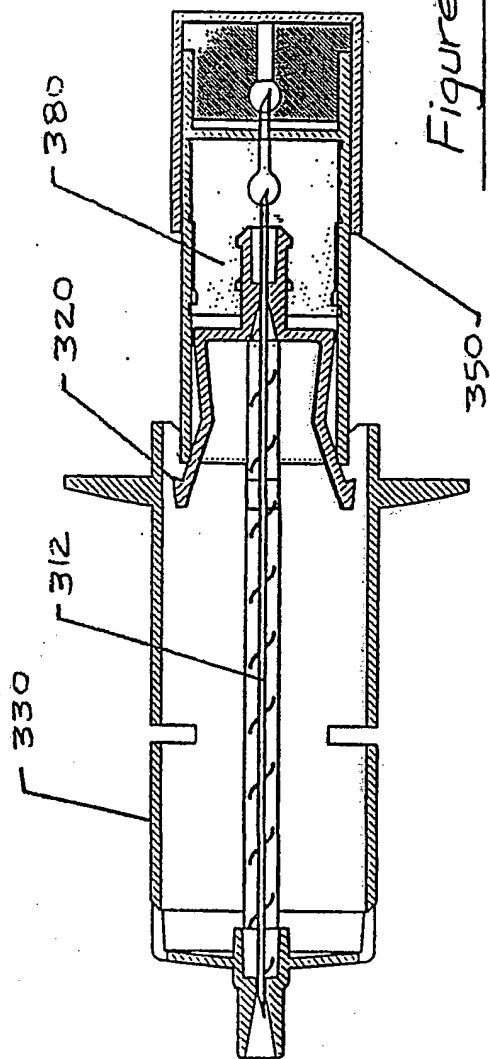


Figure 29

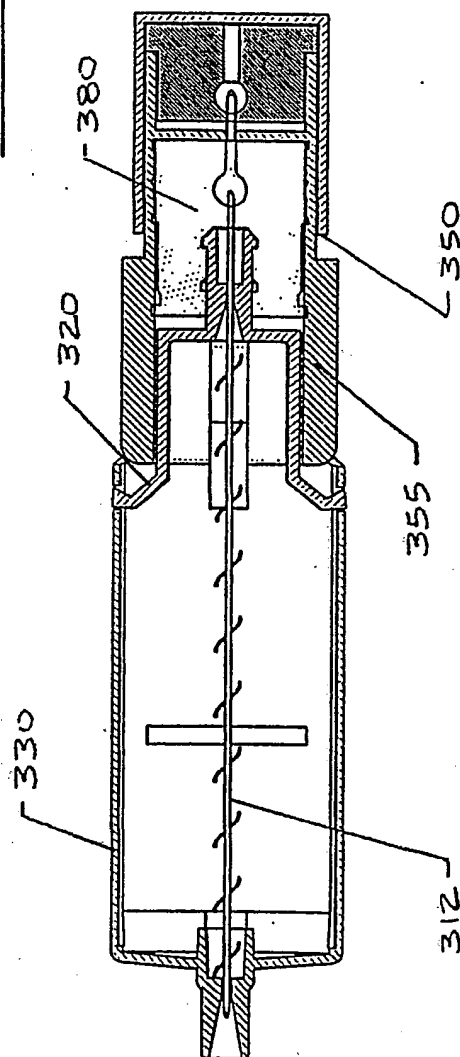


Figure 28

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